

US3832014 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:59:05

All time stamps listed in this document are displayed in GMT

US3832014

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

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[Participant ID](#)

US3832014

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

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US3832014

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3832014

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Date of Birth (MMM yyyy)	(b) (6) 1963
Age	56
Age Units	YEARS
Age (Derived)	56
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 13:56:35

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Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 2020

Year of Informed Consent (derived) 2020

Protocol Version Amendment 1 ☒  
Amendment 2 ☐  
Amendment 3 ☐  
Amendment 4 ☐  
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒  
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐  
Inclusion/Exclusion ☐  
Cohort Full ☐  
Other ☐

If reason for screen fail is Other, specify \_\_\_\_\_  
Was this participant screened previously? Yes ☐  
No ☒

If Yes, previous participant number \_\_\_\_\_  
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

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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) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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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) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Start Year (derived)	1999
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	CHRONIC COUGH
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832014

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	PLEURISY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	BENIGN TUMOR RIGHT ARM
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1992
Start Year (derived)	1992
Stop Month and Year (derived)	JAN 1992
Stop Year (derived)	1992

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	BENIGN LEFT BREAST MASS
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	BROKEN LEFT ANKLE
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2001
Start Year (derived)	2001
Stop Month and Year (derived)	JAN 2001
Stop Year (derived)	2001

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	MUSCLE SPASMS
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	COMPLETE HYSTERETOMY
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 13:56:35

Generated On: 10 Jun 2021 09:59:05

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

US3832014

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	31 JUL 2020
Time of assessment ( <i>00:00-23:59</i> )	14:18 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:18
Height ( <i>xxx.x</i> )	66 in
Weight ( <i>xxx.x</i> )	182 lb
BMI ( <i>xxx.x</i> )	29.43699 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) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Date of assessment (dd MMM yyyy) 31 JUL 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2000

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 13:56:36

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



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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 142473

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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)	31 JUL 2020
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 14:18
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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)	31 JUL 2020
Time of assessment (00:00-23:59)	15:00 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:00
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 14:30 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 14:30

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) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	14:24 (24 HR)
Collection date and time (derived)	31 JUL 2020 14:24



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:23	31 JUL 2020 14:23
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 JUL 2020 14:50

PC Close Date & Time

31 JUL 2020 17:20

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

02 AUG 2020 10:39

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 12:00

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

31 JUL 2020 14:50

PC Close Date & Time

31 JUL 2020 17:20

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 10:42

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

02 AUG 2020 12:01

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**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)**

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**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 ☐

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Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 14:50

PC Close Date & Time

31 JUL 2020 17:20

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

31 JUL 2020 18:15

PC Close Date & Time

01 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 10:41
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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)

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 12:01
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Yes ☐

PC Time stamp

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 ☐

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Yes ☐

PC Time stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

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EAB) (1725)

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US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Yes ☐

PC Time stamp

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

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)	28 AUG 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 11:48
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	163 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

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)	28 AUG 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 12:43
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	99 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 12:13 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 12:13

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

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

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

Collection date (dd MMM yyyy)	28 AUG 2020
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Collection time (00:00-23:59)	12:06 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 AUG 2020 12:06
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US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:03	28 AUG 2020 12:03
Nasopharyngeal Swab 2	No		

US3832014

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:36

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**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

98.6 °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

28 AUG 2020 14:49

PC Open Date & Time

28 AUG 2020 12:33

PC Close Date & Time

28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °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	28 AUG 2020 16:21
PC Open Date & Time	28 AUG 2020 15:58
PC Close Date & Time	29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 21:20

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 12:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

31 AUG 2020 12:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

01 SEP 2020 12:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

03 SEP 2020 10:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

03 SEP 2020 12:01

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**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

28 AUG 2020 14:49

PC Open Date & Time

28 AUG 2020 12:33

PC Close Date & Time

28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**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

28 AUG 2020 16:22

PC Open Date & Time

28 AUG 2020 15:58

PC Close Date & Time

29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 AUG 2020 21:21

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

30 AUG 2020 12:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 12:17

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 12:08

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**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

03 SEP 2020 10:57

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**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

03 SEP 2020 12:02

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**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 ☐

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:50
PC Open Date & Time	28 AUG 2020 12:33
PC Close Date & Time	28 AUG 2020 15:03

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**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 ☐

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 16:23
PC Open Date & Time	28 AUG 2020 15:58
PC Close Date & Time	29 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 21:22
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 12:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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

104 of 2684

EAB) (1725)

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 12:18
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 12:09
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 10:58
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**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 ☒

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 12:02
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59



US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:34

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 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

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 OCT 2020
Time of assessment (00:00-23:59)	10:38 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:38
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	100 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	10:53 (24 HR)
Collection date and time (derived)	1 OCT 2020 10:53

US3832014

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 13:56:45

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 OCT 2020 08:52:52

Patient Cloud Open Date & Time

30 SEP 2020 00:01

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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

09 OCT 2020 14:40:58

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

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

16 OCT 2020 09:40:37

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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

28 OCT 2020 01:18:50

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 09:53:50

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59



US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 106

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 01:17:36

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT	DAY 113
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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 23:59:50

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 15:18:13
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 08:55:44

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 00:02:13

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 16:31:49

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 02:10:49

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 00:02:54

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 10:57:32

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 06:49:49

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 02:27:43

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 JAN 2021 00:51:41
Patient Cloud Open Date & Time	31 JAN 2021 00:01
Patient Cloud Close Date & Time	04 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 00:40:40
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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 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	14 FEB 2021 00:10:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 02:10:53

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 00:46:47

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 17:41:19

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 MAR 2021 18:08:40

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 09:10:34

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:18:08

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

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

05 APR 2021 08:56:38

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 01:04:37

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 10:00:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 16:31:10

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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10 JUN 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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="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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

20 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

11 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐ 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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

25 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	26 SEP 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2021 23:59
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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐ 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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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10 FEB 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

20 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

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**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 APR 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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°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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐ 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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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02 JUN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 684

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

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

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

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

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

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

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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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="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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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



US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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31 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 AUG 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	21 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	25 AUG 2022 23:59
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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐ 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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**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 ☐ 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 ☐

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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 <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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3832014

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

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"/>

**US3832014**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	02 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	06 OCT 2022 23:59
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US3832014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:59:05

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 00:46:07

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3832014

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

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) \_\_\_\_\_

US3832014

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

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.*

US3832014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 MAR 2021
Collection time (00:00-23:59)	13:06 (24 HR)
Collection date and time (derived)	15 MAR 2021 13:06

US3832014

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3832014**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

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*

**US3832014**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3832014**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:59:05**

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"/>

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3832014

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

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

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

Visit date (dd MMM yyyy)	28 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3832014

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Date of updated informed consent ( <i>dd MMM yyyy</i> )	28 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	28 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3832014

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

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

US3832014

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 FEB 2021
Time of assessment (00:00-23:59)	15:24 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 15:24
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG



US3832014

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 FEB 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 16:06
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 FEB 2021

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

US3832014

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 1 FEB 2021

What was the treatment time? (00:00-23:59) 15:35 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 15:35

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

US3832014

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

28 JAN 2021

Collection time (00:00-23:59)

14:55 (24 HR)

Collection date and time (derived)

28 JAN 2021 14:55

US3832014

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	14:47
Collection Date and Time (derived)	28 JAN 2021 14:47

US3832014

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

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



US3832014

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	13:17 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 13:17
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 MAR 2021
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	15 MAR 2021 14:30
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3832014

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

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.*

US3832014

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 15 MAR 2021

What was the treatment time? (00:00-23:59) 13:26 (24 HR)

Treatment Date and Time (derived) 15 MAR 2021 13:26

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

US3832014

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832014

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832014

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 22:59:12

Generated On: 10 Jun 2021 09:59:05

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3832014**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

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 \_\_\_\_\_

US3832014

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

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

US3832014

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

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.*

**US3832014**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date ( <i>dd MMM yyyy</i> )	<hr/>
Collection time ( <i>00:00-23:59</i> )	<hr/>
Collection date and time (derived)	<hr/>

US3832014

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID	USA-US100-2020-MRNA-1273-P30 1000003
Adverse event	HYPERTENSIVE EMERGENCY
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)	31 AUG 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)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	02 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:11:57

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

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

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BASED ON REVIEW OF  
MEDICAL RECORDS RECEIVED  
ON 01 OCT 2020 THE  
FOLLOWING INFORMATION  
HAS BEEN UPDATED  
ADMISSION DATE 31 AUG 2020  
DISCHARGE DATE 02 SEP 2020  
ADMIN DIAGNOSIS  
HYPERTENSIVE EMERGENCY  
(LIKELY CAUSED BY ACUTE  
BACK PAIN WHICH RESULTED  
IN HYPERTENSION,  
TACHYCARDIA AND ANXIETY).  
08/31/2020 SUBJECT WAS SEEN  
IN THE ER EARLY IN THE DAY  
FOR ABDOMINAL PAIN. THE  
SUBJECT WAS TREATED WITH  
MORPHINE FOR PAIN AND HAD  
A CT SCAN OF ABDOMEN AND  
PELVIS WHICH WERE BOTH  
FOUND TO BE WITHIN NORMAL  
LIMITS WITH NO SPECIFIC  
CAUSE FOR PAIN. THE SUBJECT  
LATER RETURNED THAT DAY  
WITH SEVERE HEADACHE AND  
LEFT UPPER QUADRANT  
ABDOMINAL PAIN. THE  
SUBJECT WAS FOUND ON THE  
BATHROOM FLOOR. IT IS  
UNCLEAR HOW SHE ENDED UP  
ON THE BATHROOM FLOOR.  
VITALS OBTAINED 08/31/2020  
AT 1402 BY ER TRIAGE WITH  
THE FOLLOWING FINDINGS: HR  
113 B/P 242/136. SUBJECT WAS



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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:11:57

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---

ADMITTED AT THIS TIME  
POINT WITH NONDESCRIPT  
ABDOMINAL PAIN, WITH  
NOTED NEGATIVE X-RAY AND  
CT. CONCERN WAS NOTED  
THAT THIS EPISODE MAY BE  
REPRESENTATIVE OF  
WITHDRAWAL SINCE THE  
SUBJECT HAS NOT BEEN ON  
HER PAIN MEDICATION FOR  
THE BETTER PART OF THE  
DAY. THE SUBJECT REMAINS  
CONFUSED AND GIVEN THE  
HYPERTENSIVE EMERGENCY,  
STROKE HAS BEEN NOTED AS  
A DIFFERENTIAL, BUT  
FORTUNATELY SHE HAS NO  
ACUTE UNILATERAL DEFICITS.  
SUBJECT WAS ADMITTED TO  
ICU WITH THE FOLLOWING  
PLAN:  
HYPERTENSIVE EMERGENCY:  
STARTED ON A CARDENE DRIP  
AND AN ECHO. ECHO WNL  
ALTERED MENTAL STATUS:  
STAT CT OF HEAD WNL  
HYPERGLYCEMIA: MONITOR  
WITH COLLECTION OF A  
HGA1C  
ELEVATED BRAIN  
NATRIURETIC PEPTIDE LEVEL:  
CONTINUE TO MONITOR  
ABDOMINAL PAIN: CT  
COMPLETED WNL WITH NO

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

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ACUTE PATHOLOGY.  
ALL COLLECTED  
INFORMATION AND  
CONMENDS HAVE BEEN  
UPDATED.

---

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

---

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID

Adverse event

ALTERED MENTAL STATUS

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID

Adverse event

HYPERGLYCEMIA

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

2 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 15 Apr 2021 22:11:57

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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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID

Adverse event

ELEVATED BRAIN  
NATRIURETIC PEPTIDE LEVEL

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)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 15 Apr 2021 22:11:57

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID

Adverse event

ABDOMINAL PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID

Adverse event

ACUTE BACK PAIN

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

31 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

02 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 15 Apr 2021 22:11:57

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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 ☒  
Related ☐  
Not Applicable ☐

Relationship to Study Procedure Not Related ☒  
Related ☐  
Not Applicable ☐

Action taken with investigational product None ☐  
Dose Delayed ☐  
Investigational Product ☐  
Withdrawn ☐  
Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐  
Not Recovered/Not Resolved ☐  
Recovered/Resolved ☒  
Recovered/Resolved with Sequelae ☐  
Recovering/Resolving ☐  
Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative NOTED IN RECORDS REVIEWED FOR HYPERTENSIVE EMERGENCY AS THE LIKELY CAUSE OF HYPERTENSION, TACHYCARDIA, AND ANXIETY

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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

AEID	USA-US100-2020-MRNA-1273-P30 1000003
Adverse event	SINUS TACHYCARDIA
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)	31 AUG 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)	02 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	31 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	02 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 15 Apr 2021 22:11:57

Generated On: 10 Jun 2021 09:59:05

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	NOTED IN RECORDS REVIEWED FOR HYPERTENSIVE EMERGENCY AS THE LIKELY CAUSE OF HYPERTENSION, TACHYCARDIA, AND ANXIETY
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Data signed:** (b) (4) 15 Apr 2021 22:11:57

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

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0

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

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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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US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication SPIRIVA HANDIHALER

Prophylaxis Yes ☐  
No ☒

Indication COPD- CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2013
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) 21 Feb 2021 16:55:51

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Name of Medication COMBIVENT

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 100/20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2013	
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 (3)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication CLONIDINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 0.3

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

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) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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 2010	
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 (4)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication XOPENEX

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 1.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2013	
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 (5)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication FLOVENT

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 88

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 (5)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2013
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 (6)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication HYDROMET 5 MG-1.5 MG/5 ML  
ORAL SYRUP  
[HYDROCODONE/HOMATROPIN  
E]

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify <hr/>		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date (dd MMM yyyy) <hr/>		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
Separate Dosage Number (derived)	<hr/>	
Interval Dosage Unit Number (derived)	<hr/>	
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 (7)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication PERCOCET

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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 2010	
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 (8)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication TIZANIDINE

Prophylaxis Yes ☐  
No ☒

Indication MUSCLE SPASMS IN THE  
LOWER BACK

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2013
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)	4	
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 (9)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSIVE EMERGENCY

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

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) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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 (10)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication MAALOX PLUS(DRIED  
ALUMINIUM HYDROXIDE GEL  
,MAGNESIUM HYDROXIDE  
SIMETICONE, AND  
SORBITOL)

Prophylaxis Yes ☒  
No ☐

Indication REFLUX PROPHYLAXIS

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 ☐

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Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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) 01 SEP 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 (11)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication ADMELOG

Prophylaxis Yes ☐  
No ☒

Indication HYPERGLYCEMIA

Dose per administration 1-10

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 (11)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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"/>

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication ATIVAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSIVE EMERGENCY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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)		01 SEP 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"/>



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSIVE EMERGENCY

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

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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"/>

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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)		01 SEP 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"/>

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication CARDENE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSIVE EMERGENCY

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

5-15MG/HR

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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)		01 SEP 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) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication ZOFRAN

Prophylaxis Yes ☒  
No ☐

Indication NAUSEA PROPHYLAXIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 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)		01 SEP 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) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication PERCOCET

Prophylaxis Yes ☐  
No ☒

Indication ABDOMINAL PAIN

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication PROTONIX

Prophylaxis Yes ☒  
No ☐

Indication ACID REFLUX PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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 (19)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

Name of Medication GLYCOLOX

Prophylaxis Yes ☒  
No ☐

Indication CONSTIPATION PROPHYLAXIS

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 ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 21 Feb 2021 16:55:51

Generated On: 10 Jun 2021 09:59:05

	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)		01 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) 01 SEP 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"/>

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 16:55:52

Generated On: 10 Jun 2021 09:59:05

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 AUG 2020	ECHOCARDIOGRAM	Adverse Event	
31 AUG 2020	CT SCAN OF PELVIS AND ABDOMEN	Adverse Event	
31 AUG 2020	CT SCAN OF HEAD	Adverse Event	



US3832014

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:59:05

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 ☐

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	20/SEP/2020 13:49
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	15/OCT/2020 08:16
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	16/OCT/2020 12:54
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/NOV/2020 14:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	12/NOV/2020 17:08
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	26/JAN/2021 19:07
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/FEB/2021 13:18
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

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 08 Mar 2021 12:04:42

Generated On: 10 Jun 2021 09:59:05

SAEID	USA-US100-2020-MRNA-1273-P301000003
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	GOWDHAMI
Investigator's Last Name	MOHAN
Site Address: Street	1655 E. GREENVILLE ST
Site Address: City	ANDERSON
Site Address: State	SC
Site Address: Postal Code	29621
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	24/FEB/2021 08:18
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

US3832014 (Prod: Keystone VitaLink Research - Anderson - PPDS)

**US3832014**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:59:05**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'US3832014'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:16

**US3832014**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:29

US3832014

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:17

**US3832014**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:04
User entered 'Clinic (Clinic)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:29

**US3832014**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'SCRN'	System	01 Aug 2020 21:58:29



US3832014

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:59:05

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered (b) (6) 1963'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:18

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '56'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'YEARS'	System	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '56'	System	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered 'Female (F)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered 'l'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47



**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

**US3832014**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:59:05**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:49:37
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 21:58:47

US3832014

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:59:05

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06



**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jul 2020'	System	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2020'	System	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'Amendment 1 (1)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:06

**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Sep 2020 14:30:19
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 17:34:17



**US3832014**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:59:05**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'I'	System	01 Aug 2020 21:59:11

**US3832014**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:50:32
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:11

**US3832014**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:59:05**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:50:56
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 21:59:23

US3832014

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User closed query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 09:09:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 11:52:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 11:52:39
Data point term sent to Coder	System	21 Sep 2020 11:51:43
Query 'Per MM, please expand the abbreviation.' answered with 'Chronic obstructive pulmonary disease' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:09
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:03
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	21 Sep 2020 11:51:03
User opened query 'Per MM, please expand the abbreviation.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:54:16
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:40
User entered 'COPD'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1999'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:47



**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1999'	System	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1999'	System	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:03:47

**US3832014**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:03:47

US3832014

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
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) (b) (4)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:39
User entered 'HYPERTENSION'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:12



**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2010'	System	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2010'	System	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:12

**US3832014**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:12

US3832014

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:59:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:05:13
Data point term sent to Coder	System	01 Aug 2020 22:04:40
User entered 'CHRONIC COUGH'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:29



**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2010'	System	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2010'	System	01 Aug 2020 22:04:29

**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:29



**US3832014**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:29

US3832014

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:59:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Pleural disorders, HLT: Pleural infections and inflammations, PT: Pleurisy, LLT: Pleurisy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:25:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 17:25:36
Data point term sent to Coder	System	24 Aug 2020 17:25:10
User closed query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' (Site from System).	System	24 Aug 2020 17:24:50
Query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' answered with 'data corrected' (Site from System).	(b) (4), (b) (6)	24 Aug 2020 17:24:50
User entered 'Pleurisy' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 17:24:38
User opened query 'For coding purposes, please split to report each event separately to capture coding for all terms. Example: 1) CHEST PAIN (Specify if cardiac or non-cardiac) 2) LUNG PAIN' (Site from System).	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:41:58
Data point term sent to Coder	System	01 Aug 2020 22:05:41
User entered 'CHEST/LUNG PAIN'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2010'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2010'	System	01 Aug 2020 22:04:59



**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2010'	System	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:59

**US3832014**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:04:59

US3832014

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:59:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Cutaneous neoplasms benign, HLT: Skin neoplasms benign, PT: Benign neoplasm of skin, LLT: Benign neoplasm of skin - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:27:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 15:27:10
Data point term sent to Coder	System	01 Aug 2020 22:05:41
User entered 'BENIGN TUMOR RIGHT ARM'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4)	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4)	01 Aug 2020 22:05:35



**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1981'	System	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1981'	System	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1981'	System	01 Aug 2020 22:05:35

**US3832014**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1981'	System	01 Aug 2020 22:05:35

US3832014

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:07:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:07:13
Data point term sent to Coder	System	01 Aug 2020 22:06:41
User entered 'APPENDICITIS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1992'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:08



**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1992'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1992'	System	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1992'	System	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1992'	System	01 Aug 2020 22:06:08

**US3832014**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1992'	System	01 Aug 2020 22:06:08

US3832014

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms benign (incl nipple), HLT: Breast and nipple neoplasms benign, PT: Benign breast neoplasm, LLT: Breast lump (benign) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:47:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Aug 2020 13:47:16
Data point term sent to Coder	System	01 Aug 2020 22:07:42
User entered 'BENIGN LEFT BREAST MASS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:06:50



**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 1981'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1981'	System	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1981'	System	01 Aug 2020 22:06:50

**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 1981'	System	01 Aug 2020 22:06:50



**US3832014**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '1981'	System	01 Aug 2020 22:06:50

US3832014

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:59:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Ankle fracture, LLT: Broken ankle - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 07:31:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 07:31:00
Data point term sent to Coder	System	01 Aug 2020 22:07:42
User entered 'BROKEN LEFT ANKLE'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2001'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2001'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2001'	System	01 Aug 2020 22:07:16



**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2001'	System	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2001'	System	01 Aug 2020 22:07:16

**US3832014**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2001'	System	01 Aug 2020 22:07:16

US3832014

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:08:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Aug 2020 22:08:14
Data point term sent to Coder	System	01 Aug 2020 22:07:44
User entered 'MUSCLE SPASMS'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'UN UNK 2013'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:38



**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2013'	System	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2013'	System	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:07:38

**US3832014**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	01 Aug 2020 22:07:38

US3832014

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:26:27
Data point term sent to Coder	System	19 Oct 2020 19:25:34
User entered 'Menorrhagia'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4)	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 19:24:37



**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4)	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2000'	System	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2000'	System	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2000'	System	19 Oct 2020 19:24:37

**US3832014**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2000'	System	19 Oct 2020 19:24:37

US3832014

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:59:05

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:51:21
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:20:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 00:20:29
Data point term sent to Coder	System	19 Oct 2020 19:27:41
User entered 'COMPLETE HYSTERETOMY' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:27:04
Data point term sent to Coder	System	19 Oct 2020 19:26:37
User entered 'Complete Hysterotomy'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:25:55



**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4)	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered 'un UNK 2000'	Danyel Johnson (b) (4)	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:51:21
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2000'	System	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2000'	System	19 Oct 2020 19:25:55

**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2000'	System	19 Oct 2020 19:25:55



**US3832014**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2000'	System	19 Oct 2020 19:25:55

US3832014

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:59:05

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:50:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	25 Jan 2021 18:50:50
Data point term sent to Coder	System	25 Jan 2021 18:50:11
User entered 'Anxiety'	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'un UNK 2010'	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty.	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'Jan 2010'	System	25 Jan 2021 18:49:15



**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '2010'	System	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered empty.	System	25 Jan 2021 18:49:15

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '14:18'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered '31 Jul 2020 14:18'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '66' in	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11



US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '182' lb	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
Amendment Manager: User entered '29.43699'	System	16 Sep 2020 23:39:49
User entered '29.4'	System	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'kg/m2'	System	01 Aug 2020 22:01:02
DataPoint set to visible.	System	01 Aug 2020 21:59:11

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:08
Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:25
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:28
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:15
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:13
User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:13:24
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '98.6' F	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:12
Query 'please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:30
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:27
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:14:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:15
Query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:14:59
User opened query 'please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:14:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '84'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'bpm'	System	01 Aug 2020 22:01:02



US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:18
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:26
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:15:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '15'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'breaths/min'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:21
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:42
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:15:31
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '128'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'mmHg'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 22:18:24
Query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:53
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Nov 2020 22:16:01
User opened query 'Please enter ND. per EDC guidelines, if Day 0 and Day 1 are performed same date, then this is only entered on Day 1.' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:15:59
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:30
User entered '83'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:02

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User entered 'mmHg'	System	01 Aug 2020 22:01:02

US3832014

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23

**US3832014**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23



**US3832014**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:53:42
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:17

US3832014

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:53:42
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:03:54
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		28 Aug 2020 16:21:18
User entered '31 Jul 2020'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:17

**US3832014**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:59:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:05

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:58:03
User closed query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	01 Aug 2020 22:02:18
User entered 'No (N)' reason for change: Data Entry Error	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:02:18
User opened query 'Is the participant of childbearing potential is Yes, however information below has been provided. Please correct.' (Site from System).	System	01 Aug 2020 22:01:36
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:05

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:59:55
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'Data has been updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:28:16
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 04:49:51
User entered 'Surgically sterile (SURGICALLY STERILE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

**US3832014**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:59:05**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

US3832014

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:58:03
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	31 Aug 2020 21:31:20
User entered 'UN UNK 2000' reason for change: Per Alyssa-Kay Peay Query Resolution	(b) (4)	31 Aug 2020 21:31:20
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	01 Aug 2020 22:02:18
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:01:36

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:59:05**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36



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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

**US3832014**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:59:05**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:03
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:01:36

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05



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Folder: Screening

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

**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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

[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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

**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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

**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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:59:05**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:42:34
Query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:04:28
User opened query 'Please select living condition. Please note, one of the options below needs to selected. If selecting "other", please specify (IE Homeless)' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:01:16
User closed query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	02 Aug 2020 16:46:05
User entered '0' reason for change: Data Entry Error	Ashten Sheriff (b) (4) (b) (4)	02 Aug 2020 16:46:05
User opened query 'No Risk Identified' checked and other selections were checked as well. Please review and reconcile.' (Site from System).	System	02 Aug 2020 16:45:56
User entered '1'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

**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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

**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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

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)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '0'	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:58:39
User entered '1' reason for change: Data Entry Error	Ashten Sheriff (b) (4)	02 Aug 2020 16:45:56
User entered '0'	(b) (4) Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	08 Nov 2020 21:59:58
Query 'please delete' answered with 'Update per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:32:19
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	03 Nov 2020 16:32:13
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 22:23:00
User entered '1' reason for change: Data Entry Error	Ashten Sheriff (b) (4) (b) (4)	02 Aug 2020 16:45:56
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:03:05

US3832014

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:59:05

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:11:23
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'This section is for living conditions. please delete. ' (Site from CRA).	(b) (4)	
Query 'This section is for living conditions. please delete. ' answered with 'Update per query ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:00:04
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	03 Nov 2020 16:32:24
DataPoint Un-verified.	(b) (4)	
User opened query 'This section is for living conditions. please delete. ' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 16:32:13
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 22:42:46
User entered 'participant plans on routinely (e.g., weekly) going to places where people gather (e.g., places of worship, restaurants, bars, sporting events) over the coming months' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Nov 2020 22:42:45
User entered empty.	(b) (4), (b) (6)	27 Oct 2020 15:58:39
	Ashten Sheriff (b) (4)	02 Aug 2020 16:45:56
	(b) (4)	
	Ashten Sheriff (b) (4)	01 Aug 2020 22:03:05
	(b) (4)	

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:17



**US3832014**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:17

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:38
User entered 'Clinic (Clinic)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:17

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'VISIT1'	System	01 Aug 2020 22:08:17

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered '31 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:05

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:59:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:31:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:31:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 18:14:12
User entered '142473' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 18:14:12

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:05

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)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:59:05

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)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:47



**US3832014**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:47

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:59:05**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:47

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:59:05**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:59:46
User entered 'No (N)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:08:47

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User accepted default value 'Pre-Dose (PREDOSE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15



US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '14:18'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered '31 Jul 2020 14:18'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '98.6' F	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '84'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15



US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'bpm'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '15'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'breaths/min'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '128'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:10:58
User entered '83'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:53
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:22
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:03
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:00
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:04
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:14
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:17
User entered '66' in	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15



US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:34:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'Updated per query ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:52
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 20:55:31
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
User closed query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:44:33
Query 'Per query response, ND. Please enter ND into the database.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:05:09
User opened query 'Per query response, ND. Please enter ND into the database.' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 21:57:09
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:13:07
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:12:57
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:19
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:11:16
User entered '182' lb	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User accepted default value 'Post-Dose (POSTDOSE)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:12:20
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)	10 Aug 2020 17:05:28
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 minutes post dose' (Site from System).	Ashten Sheriff (b) (4) (b) (4)	02 Aug 2020 16:44:01
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).		01 Aug 2020 22:12:48
User entered '15:00'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered '31 Jul 2020 15:00'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '98.3' F	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered 'Oral (Oral)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15



US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '73'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'bpm'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '14'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'breaths/min'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '128'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:20
User entered '78'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:15



US3832014

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'mmHg'	System	01 Aug 2020 22:12:15

US3832014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:43:40
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	09 Nov 2020 21:03:45
Query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:04:51
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	09 Nov 2020 16:04:44
User opened query 'Per EDC guidelines, NO should be selected if Day 0 and Day 1 are performed the same day. ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:00
User closed query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:00
Query 'Data is required. Please complete.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:57
Query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:54
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Nov 2020 18:34:50
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:50
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 18:34:50
User opened query 'Per EDC guidelines, NO must be recorded if Day 0 and Day 1 are performed on the same date, this is only entered on Day . Please verify and reconcile ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:41

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:27
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:29

US3832014

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User closed query 'please remote date, enter NO' (Site from CRA).	(b) (4)	
Query 'please remote date, enter NO' answered with 'ND' (Site from CRA).	(b) (4), (b) (6)	08 Nov 2020 22:08:05
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:59
	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:50
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:34:50
	(b) (4)	
User opened query 'please remote date, enter NO' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 16:35:54
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:12:27
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:29
	(b) (4)	

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered empty.	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

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)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'MRNA-1273 OR PLACEBO'	System	01 Aug 2020 22:12:48



US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered '14:30'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:48

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered '31 Jul 2020 14:30'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'Right Arm (RIGHT ARM)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:13:25
User entered 'ONCE'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'INTRAMUSCULAR'	System	01 Aug 2020 22:12:48

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:02



**US3832014**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:06
User entered '14:24'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:02

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered '31 Jul 2020 14:24'	System	01 Aug 2020 22:13:02

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '31 Jul 2020'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '14:23'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered '31 Jul 2020 14:23'	System	01 Aug 2020 22:13:25

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Ashten Sheriff (b) (4) (b) (4)	01 Aug 2020 22:13:25



US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25
	(b) (4)	

US3832014

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:20:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:38
User entered '14:23'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:25
	(b) (4)	

**US3832014**

**Folder: Visit 1 Day 1**

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

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered empty.	System	10 Nov 2020 21:20:10
User entered '31 Jul 2020 14:23'	System	01 Aug 2020 22:13:25

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:14:49
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	01 Aug 2020 22:13:30

**US3832014**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'I'	System	01 Aug 2020 22:13:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:38:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered 'Yes (Y)'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:38:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '98.9'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:07', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered 'Yes (Y)'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
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 'Subject contacted for Day 8 safety call. Subject taking percocet PRN for pain as baseline therapy. Subject denied taking any additional medications for pain or fever.' (Site from System).	(b) (4), (b) (6)	25 Aug 2020 08:38:47
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).	(b) (4), (b) (6)	24 Aug 2020 17:16:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '1'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '0'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:39:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '25121e52-09bb-4553-bcbc-0351ca92b605'	System	02 Aug 2020 14:39:30
User entered '02 Aug 2020 10:39'	System	02 Aug 2020 14:39:30

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered 'Yes (Y)'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f' User entered '98.3'	System	02 Aug 2020 16:01:05
	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered 'No (N)'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:00:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '04085e4d-35c8-4920-8318-955917f2c60f'	System	02 Aug 2020 16:01:05
User entered '02 Aug 2020 12:00'	System	02 Aug 2020 16:01:05

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:07', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'None (1)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'No (N)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'No (N)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered 'None (1)'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:42:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b3e58f67-5903-4b66-b26d-6ae4634c0cfc'	System	02 Aug 2020 14:42:25
User entered '02 Aug 2020 10:42'	System	02 Aug 2020 14:42:25

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'None (1)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'No (N)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'No (N)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered 'None (1)'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '79e4cb37-56e0-4121-8022-500f065b28d8'	System	02 Aug 2020 16:01:17
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:17

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

**US3832014**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 14:50'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 17:20'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 1, after vaccination (at home)'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Jul 2020 18:15'	System	01 Aug 2020 22:12:48

**US3832014**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 2'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:47', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:40:57', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'None (0)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered 'No (N)'	System	02 Aug 2020 14:41:15

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T10:41:10', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ffc59e79-ff75-4d80-8e44-e57c81c2f645'	System	02 Aug 2020 14:41:15
User entered '02 Aug 2020 10:41'	System	02 Aug 2020 14:41:15

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 11:59'	System	01 Aug 2020 22:12:48



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 3'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:30', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'None (0)'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered 'No (N)'	System	02 Aug 2020 16:01:49



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (40f8709ae304b723)', Time: '2020-08-02T12:01:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b7017818-f630-4d2f-8982-99416f7c9cf6'	System	02 Aug 2020 16:01:49
User entered '02 Aug 2020 12:01'	System	02 Aug 2020 16:01:49

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 4'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 5'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Aug 2020 12:00'	System	01 Aug 2020 22:12:48



**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 6'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '05 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 7'	System	01 Aug 2020 22:12:48

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43



US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

US3832014

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '06 Aug 2020 12:00'	System	01 Aug 2020 22:12:48

**US3832014**

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

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

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '07 Aug 2020 11:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Aug 2020 18:51:46



**US3832014**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered '07 Aug 2020'	Alyssa-Kay Peay (b) (4)	07 Aug 2020 18:51:46

**US3832014**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:15:17
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	07 Aug 2020 18:51:46

US3832014

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:23
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Aug 2020 18:51:50

**US3832014**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'I'	System	07 Aug 2020 18:51:50

**US3832014**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:28:33

**US3832014**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered '17 Aug 2020'	Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33



US3832014

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 16:15:43
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	17 Aug 2020 16:28:33

US3832014

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	17 Aug 2020 16:28:18

**US3832014**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 09:28:46
User entered 'I'	System	17 Aug 2020 16:28:18

**US3832014**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:12

**US3832014**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '21 Aug 2020'	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:12

**US3832014**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:12

**US3832014**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:12

US3832014

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	21 Aug 2020 13:48:00



**US3832014**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:25:09
User entered 'I'	System	21 Aug 2020 13:48:00

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:18

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:05

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:18

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'VISIT2'	System	28 Aug 2020 16:21:18

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55



**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '11:48'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '28 Aug 2020 11:48'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '98.2' F	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '74'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'bpm'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '14'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55



US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'breaths/min'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	16 Sep 2020 23:39:49
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 17:00:55
User entered '163'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '93'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55



**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '12:43'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '28 Aug 2020 12:43'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '98.5' F	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Oral (Oral)'	(b) (4) Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '69'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'bpm'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '16'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55



US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'breaths/min'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
Amendment Manager: User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) System	16 Sep 2020 23:39:49
Amendment Manager: Query 'Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	16 Sep 2020 23:39:49
Amendment Manager: Query text changed to "Systolic Blood Pressure reported is out of range < 80 or > 200 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate."	System	16 Sep 2020 23:39:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 17:00:55
User entered '162'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '99'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	16 Sep 2020 17:00:55

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:22

US3832014

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:22

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41



US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty.	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty.	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '12:13'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '28 Aug 2020 12:13'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Right Arm (RIGHT ARM)'	Alyssa-Kay Peay (b) (4)	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'ONCE'	System	28 Aug 2020 16:21:41



US3832014

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 16:21:41

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '28 Aug 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:38

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '12:06'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:38

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '28 Aug 2020 12:06'	System	16 Sep 2020 17:05:38

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User closed query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "28AUG2020", please review and confirm the sample details, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm the accession number " 1F621465612" given in the response belongs to "US3832011" subject ID, Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 09:24:09
Query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "28AUG2020", please review and confirm the sample details, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm the accession number " 1F621465612" given in the response belongs to "US3832011" subject ID, Please reconcile the data and update as appropriate. Else clarify, thank you.' answered with 'Accession number swab 1F621465612 should be for subject US3832014 Day 29 and accession number Swab 1F619721926 should be for subject 2011 V2 Day 29. The Uns is noted in error for subject US3832011' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	24 Mar 2021 21:15:03
User opened query 'Per GCL Lab Recon: Swab: Response noted, however, per Preclarus report, there is no record of this subject ID with SWAB sample collected on "28AUG2020", please review and confirm the sample details, and if there is any SUBJECT ID entry error or ID mismatch, as there is no record of this subject ID per Preclarus report. Please also confirm the accession number " 1F621465612" given in the response belongs to "US3832011" subject ID, Please reconcile the data and update as appropriate. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 06:36:04

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. Please provide shipment tracking details which will help us reconcile data with PPD central labs as it is still missing in GCL. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Feb 2021 07:55:27
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. Please provide shipment tracking details which will help us reconcile data with PPD central labs as it is still missing in GCL. Thank you.' answered with '1F653224684' (Site from DM).	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. Please provide shipment tracking details which will help us reconcile data with PPD central labs as it is still missing in GCL. Thank you.' (Site from DM).	(b) (4)	10 Feb 2021 15:46:02
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Feb 2021 10:53:58
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'The sample has been sent and received by Viracor, Bar code for swab 1F621465612 ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 11:11:24
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'The sample has been sent and received by Viracor, Bar code for swab 1F621465612 ' (Site from DM).	Danyel Johnson (b) (4)	07 Dec 2020 14:42:57

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 28AUG2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM). User entered '28 Aug 2020'	(b) (4), (b) (6)	07 Dec 2020 11:05:35
	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51



**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '12:03'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '28 Aug 2020 12:03'	System	16 Sep 2020 17:05:51

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	16 Sep 2020 17:05:51

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:19:49
User entered 'Yes (Y)'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51
	(b) (4)	

US3832014

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:59:05

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	10 Nov 2020 21:19:49
User entered '12:03'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 17:05:51

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered empty.	System	10 Nov 2020 21:19:49
User entered '28 Aug 2020 12:03'	System	16 Sep 2020 17:05:51



**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:40:42

**US3832014**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	07 Sep 2020 13:40:42

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered 'Yes (Y)'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered '98.6'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:48:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered 'No (N)'	System	28 Aug 2020 18:49:07

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f4a8e7ee-7a48-431e-a7cf-1d3c4ac4e23e'	System	28 Aug 2020 18:49:07
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 18:49:07

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered 'Yes (Y)'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered '98.4'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:53', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered 'No (N)'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:21:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '49beb6a9-bcbf-4793-a31c-7ff116c1b854'	System	28 Aug 2020 20:21:59
User entered '28 Aug 2020 16:21'	System	28 Aug 2020 20:21:59

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:35', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered 'Yes (Y)'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered '98.6'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered 'No (N)'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:20:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '930bc623-62b0-4b5b-b6aa-f0342e3793be'	System	30 Aug 2020 01:20:53
User entered '29 Aug 2020 21:20'	System	30 Aug 2020 01:20:53

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:31', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered 'Yes (Y)'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered '98.6'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered 'No (N)'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a5c2d42c-b5f7-44ae-8a5f-46f648722088'	System	30 Aug 2020 16:00:56
User entered '30 Aug 2020 12:00'	System	30 Aug 2020 16:00:56

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:16:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered 'Yes (Y)'	System	31 Aug 2020 16:32:49



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered '98.9'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered 'No (N)'	System	31 Aug 2020 16:32:49

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '67c5c1b6-c2f1-456e-8960-1a56eca11219'	System	31 Aug 2020 16:32:49
User entered '31 Aug 2020 12:17'	System	31 Aug 2020 16:32:49

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered 'Yes (Y)'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:39', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered '97.2'	System	01 Sep 2020 16:08:03



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:07:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered 'No (N)'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '409ffa64-0dae-46fc-a2c3-d6cd7392e9b1'	System	01 Sep 2020 16:08:03
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:08:03

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered 'Yes (Y)'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered '98.8'	System	03 Sep 2020 14:57:27

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:19', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered 'No (N)'	System	03 Sep 2020 14:57:27



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c5e512a-c8fe-4d9f-8ee7-095ac92a3c19'	System	03 Sep 2020 14:57:27
User entered '03 Sep 2020 10:57'	System	03 Sep 2020 14:57:27

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered 'Yes (Y)'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:45', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered '98.6'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered 'No (N)'	System	03 Sep 2020 16:03:32

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '21596e56-a12f-4f96-af3a-542e35a3ab3a'	System	03 Sep 2020 16:03:32
User entered '03 Sep 2020 12:01'	System	03 Sep 2020 16:03:32



US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'None (1)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'No (N)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'No (N)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered 'None (1)'	System	28 Aug 2020 18:49:38

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'ab7a1f21-b05a-4239-a06c-5124f79cfac7'	System	28 Aug 2020 18:49:38
User entered '28 Aug 2020 14:49'	System	28 Aug 2020 18:49:38



US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'None (1)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'No (N)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:10', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'No (N)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered 'None (1)'	System	28 Aug 2020 20:22:25

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:22', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '050cfbae-e0fb-490a-8a80-10ca906d98b4'	System	28 Aug 2020 20:22:25
User entered '28 Aug 2020 16:22'	System	28 Aug 2020 20:22:25



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'None (1)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:15', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'No (N)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'No (N)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered 'None (1)'	System	30 Aug 2020 01:21:33

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cc9a0be-eede-4211-8f45-b792cc863798'	System	30 Aug 2020 01:21:33
User entered '29 Aug 2020 21:21'	System	30 Aug 2020 01:21:33



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:00:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'None (1)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'No (N)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'No (N)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered 'None (1)'	System	30 Aug 2020 16:01:35

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0aab37ba-813c-47fb-b9ce-e183cbe6e936'	System	30 Aug 2020 16:01:35
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:01:35



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'None (1)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'No (N)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'No (N)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:30', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered 'None (1)'	System	01 Sep 2020 16:07:09

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:33', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '382806c5-8157-406a-948e-02cc37a4e544'	System	01 Sep 2020 16:07:09
User entered '31 Aug 2020 12:17'	System	01 Sep 2020 16:07:09



US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:14', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'None (1)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'No (N)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'No (N)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered 'None (1)'	System	01 Sep 2020 16:08:43

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '18cc5664-ce4c-44b9-9352-bf8e77a3aae1'	System	01 Sep 2020 16:08:43
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:08:43



US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'None (1)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'No (N)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:35', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'No (N)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:39', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered 'None (1)'	System	03 Sep 2020 14:57:44

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'd555d96d-a8c6-44be-b77b-cf4b89a294ab'	System	03 Sep 2020 14:57:44
User entered '03 Sep 2020 10:57'	System	03 Sep 2020 14:57:44



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:01:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'None (1)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'No (N)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'No (N)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered 'None (1)'	System	03 Sep 2020 16:03:57

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '2c6f48be-c08a-495c-94d1-51a0e534f737'	System	03 Sep 2020 16:03:57
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:03:57



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:49:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'None (0)'	System	28 Aug 2020 18:50:09

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:03', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered 'No (N)'	System	28 Aug 2020 18:50:09

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T14:50:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9cbaf891-d8b8-428c-a6ec-6576712c1ddf'	System	28 Aug 2020 18:50:09
User entered '28 Aug 2020 14:50'	System	28 Aug 2020 18:50:09

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 12:33'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:03'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'None (0)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:22:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered 'No (N)'	System	28 Aug 2020 20:23:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-28T16:23:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c867057c-c0f6-4e7d-9a39-05aa82979f8b'	System	28 Aug 2020 20:23:07
User entered '28 Aug 2020 16:23'	System	28 Aug 2020 20:23:07

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '28 Aug 2020 15:58'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 16:21:41



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 2'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'None (0)'	System	30 Aug 2020 01:22:04

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:21:59', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered 'No (N)'	System	30 Aug 2020 01:22:04



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-29T21:22:02', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b8442813-e39d-43df-b57c-0efeb291c4b5'	System	30 Aug 2020 01:22:04
User entered '29 Aug 2020 21:22'	System	30 Aug 2020 01:22:04

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:59:05

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 3'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:19', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:21', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:24', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'None (0)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered 'No (N)'	System	30 Aug 2020 16:02:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-30T12:01:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4241798a-ef74-47c8-a3c6-603f100bee77'	System	30 Aug 2020 16:02:10
User entered '30 Aug 2020 12:01'	System	30 Aug 2020 16:02:10

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 4'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:17:54', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'None (0)'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:18:05', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered 'No (N)'	System	01 Sep 2020 16:07:07

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-08-31T12:18:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a4fc7541-dce4-4570-8cbb-9fd78dc700c7'	System	01 Sep 2020 16:07:07
User entered '31 Aug 2020 12:18'	System	01 Sep 2020 16:07:07

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:59:05

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 16:21:41



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 5'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:08:55', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:01', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:18', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:25', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'None (0)'	System	01 Sep 2020 16:09:48



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered 'No (N)'	System	01 Sep 2020 16:09:48

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-01T12:09:43', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '484eac18-f972-41a0-8344-0f4a0cb0ee3e'	System	01 Sep 2020 16:09:48
User entered '01 Sep 2020 12:09'	System	01 Sep 2020 16:09:48

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 6'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:53', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:56', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:57:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'None (0)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:58:04', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered 'No (N)'	System	03 Sep 2020 14:58:10

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T10:58:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '792bb844-1f94-4701-85f8-893f67b25143'	System	03 Sep 2020 14:58:10
User entered '03 Sep 2020 10:58'	System	03 Sep 2020 14:58:10

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	28 Aug 2020 16:21:41
User entered 'Day 7'	System	28 Aug 2020 16:21:41



US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:17', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'None (0)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:43', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered 'No (N)'	System	03 Sep 2020 16:04:52

US3832014

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:59:05

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-09-03T12:02:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'c38c070d-171b-4e77-bf6b-a17ef2cd22e2'	System	03 Sep 2020 16:04:52
User entered '03 Sep 2020 12:02'	System	03 Sep 2020 16:04:52



**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 16:21:41

**US3832014**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:59:05**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 16:21:41

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13

**US3832014**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '7 Sep 2020'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13

**US3832014**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13

US3832014

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:13

US3832014

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	07 Sep 2020 13:50:18

**US3832014**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	07 Sep 2020 13:50:18



**US3832014**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	17 Sep 2020 12:21:39

**US3832014**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '11 Sep 2020'	Ashten Sheriff (b) (4)	17 Sep 2020 12:21:39

**US3832014**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Contact Made (CONTACT MADE)'	Ashten Sheriff (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty.	Ashten Sheriff (b) (4)	17 Sep 2020 12:21:39

US3832014

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	17 Sep 2020 12:21:43

**US3832014**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	17 Sep 2020 12:21:43

**US3832014**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered '18 Sep 2020'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:19:54



**US3832014**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:19:54

US3832014

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered empty.	(b) (4)	18 Sep 2020 18:19:54
	(b) (4), (b) (6)	

**US3832014**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:36
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	18 Sep 2020 18:19:57

**US3832014**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	18 Sep 2020 18:19:57

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	01 Oct 2020 15:10:03

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '1 Oct 2020'	Emma Partin (b) (4)	01 Oct 2020 15:10:03

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	01 Oct 2020 15:10:03

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'VISIT3'	System	01 Oct 2020 15:10:03



**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '1 Oct 2020'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '10:38'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '1 Oct 2020 10:38'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '98.3' F	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Oral (Oral)'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered empty.	Emma Partin (b) (4)	01 Oct 2020 15:10:45

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '73'	Emma Partin (b) (4)	01 Oct 2020 15:10:45



**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'bpm'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '16'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'breaths/min'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '162'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '100'	Emma Partin (b) (4)	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'mmHg'	System	01 Oct 2020 15:10:45

US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12



US3832014

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12

US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	01 Oct 2020 15:10:56

US3832014

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '1 Oct 2020'	Emma Partin (b) (4)	01 Oct 2020 15:10:56

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '1 Oct 2020'	Emma Partin (b) (4)	01 Oct 2020 15:11:16

US3832014

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered '10:53'	Emma Partin (b) (4)	01 Oct 2020 15:11:16

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered '1 Oct 2020 10:53'	System	01 Oct 2020 15:11:16

**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 13:56:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	01 Oct 2020 15:11:21



**US3832014**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	01 Oct 2020 15:11:21

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 64'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered 'No (N)'	System	02 Oct 2020 12:52:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:48', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered 'No (N)'	System	02 Oct 2020 12:52:55

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-02T08:52:52', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '45ec17d8-4a5b-440f-ad64-1d2ad24f1c1c'	System	02 Oct 2020 12:52:55
User entered '02 Oct 2020 08:52:52'	System	02 Oct 2020 12:52:55

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '30 Sep 2020 00:01'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '04 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 71'	System	01 Aug 2020 22:12:48



US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered 'No (N)'	System	09 Oct 2020 18:41:05

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:51', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered 'No (N)'	System	09 Oct 2020 18:41:05

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-09T14:40:58', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4fd701fe-a1ac-4b31-bcf6-6162a0b772d1'	System	09 Oct 2020 18:41:05
User entered '09 Oct 2020 14:40:58'	System	09 Oct 2020 18:41:05

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '07 Oct 2020 00:01'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '11 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 78'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered 'No (N)'	System	16 Oct 2020 13:40:42

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:31', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered 'No (N)'	System	16 Oct 2020 13:40:42



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-16T09:40:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '0a681bf6-4ff3-4b36-8497-400362c68070'	System	16 Oct 2020 13:40:42
User entered '16 Oct 2020 09:40:37'	System	16 Oct 2020 13:40:42

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '14 Oct 2020 00:01'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '18 Oct 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 92'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered 'No (N)'	System	28 Oct 2020 05:18:53

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered 'No (N)'	System	28 Oct 2020 05:18:53

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-10-28T01:18:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'bff1ed39-366f-4b89-9569-cdce85d3552c'	System	28 Oct 2020 05:18:53
User entered '28 Oct 2020 01:18:50'	System	28 Oct 2020 05:18:53

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '28 Oct 2020 00:01'	System	01 Aug 2020 22:12:48



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '01 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 99'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered 'No (N)'	System	06 Nov 2020 14:53:55

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered 'No (N)'	System	06 Nov 2020 14:53:55

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-06T09:53:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '054de2b7-5bd4-4e8b-b635-e466dd680aed'	System	06 Nov 2020 14:53:55
User entered '06 Nov 2020 09:53:50'	System	06 Nov 2020 14:53:55

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '04 Nov 2020 00:01'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '08 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 106'	System	01 Aug 2020 22:12:48



US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

[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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:09', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered 'No (N)'	System	11 Nov 2020 06:17:39

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:23', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered 'No (N)'	System	11 Nov 2020 06:17:39

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-11T01:17:36', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'cf6c7f35-6ac2-4a94-bb85-ecae2a681abc'	System	11 Nov 2020 06:17:39
User entered '11 Nov 2020 01:17:36'	System	11 Nov 2020 06:17:39

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '11 Nov 2020 00:01'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 21:17:43
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '15 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15
Data entry locked.	System	01 Aug 2020 22:12:48
User entered 'Day 113'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

US3832014

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:59:05

Have you been exposed to someone with 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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Please 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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Please 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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Please 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 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '18 Nov 2020 00:01'	System	01 Aug 2020 22:12:48



**US3832014**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:01:15
Data entry locked.	System	01 Aug 2020 22:12:48
User entered '22 Nov 2020 23:59'	System	01 Aug 2020 22:12:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered 'No (N)'	System	23 Nov 2020 04:59:55

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered 'No (N)'	System	23 Nov 2020 04:59:55

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-22T23:59:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '8278b0b6-a13a-41cf-a08e-8cf63a407402'	System	23 Nov 2020 04:59:55
User entered '22 Nov 2020 23:59:50'	System	23 Nov 2020 04:59:55

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-29T15:18:08', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5fb38ef9-9bac-40ac-abe8-7324eaa91a1f'	System	29 Nov 2020 20:18:17
User entered 'No (N)'	System	29 Nov 2020 20:18:17

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-29T15:18:10', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5fb38ef9-9bac-40ac-abe8-7324eaa91a1f'	System	29 Nov 2020 20:18:17
User entered 'No (N)'	System	29 Nov 2020 20:18:17

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-11-29T15:18:13', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5fb38ef9-9bac-40ac-abe8-7324eaa91a1f'	System	29 Nov 2020 20:18:17
User entered '29 Nov 2020 15:18:13'	System	29 Nov 2020 20:18:17

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-06T08:55:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '58beee15-cac8-4624-9148-6f193b9c5aa1'	System	06 Dec 2020 13:55:48
User entered 'No (N)'	System	06 Dec 2020 13:55:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-06T08:55:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '58beee15-cac8-4624-9148-6f193b9c5aa1'	System	06 Dec 2020 13:55:48
User entered 'No (N)'	System	06 Dec 2020 13:55:48



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-06T08:55:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '58beee15-cac8-4624-9148-6f193b9c5aa1' User entered '06 Dec 2020 08:55:44'	System	06 Dec 2020 13:55:48
	System	06 Dec 2020 13:55:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-13T00:02:01', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9e381c01-2f15-407b-8102-fe4aedee1d7e'	System	13 Dec 2020 05:02:48
User entered 'No (N)'	System	13 Dec 2020 05:02:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-13T00:02:06', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9e381c01-2f15-407b-8102-fe4aedee1d7e'	System	13 Dec 2020 05:02:48
User entered 'No (N)'	System	13 Dec 2020 05:02:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-13T00:02:13', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9e381c01-2f15-407b-8102-fe4aedeel7e'	System	13 Dec 2020 05:02:48
User entered '13 Dec 2020 00:02:13'	System	13 Dec 2020 05:02:48

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-21T16:31:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9943ac7a-2464-4714-b26e-eb868c474778'	System	21 Dec 2020 21:31:51
User entered 'No (N)'	System	21 Dec 2020 21:31:51

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-21T16:31:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9943ac7a-2464-4714-b26e-eb868c474778'	System	21 Dec 2020 21:31:51
User entered 'No (N)'	System	21 Dec 2020 21:31:51

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-21T16:31:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9943ac7a-2464-4714-b26e-eb868c474778'	System	21 Dec 2020 21:31:51
User entered '21 Dec 2020 16:31:49'	System	21 Dec 2020 21:31:51

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-27T02:10:42', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4d6d78fb-687d-4dff-961b-6f43126ebf0e'	System	27 Dec 2020 07:10:52
User entered 'No (N)'	System	27 Dec 2020 07:10:52

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-27T02:10:46', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4d6d78fb-687d-4dff-961b-6f43126ebf0e'	System	27 Dec 2020 07:10:52
User entered 'No (N)'	System	27 Dec 2020 07:10:52

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2020-12-27T02:10:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4d6d78fb-687d-4dff-961b-6f43126ebf0e'	System	27 Dec 2020 07:10:52
User entered '27 Dec 2020 02:10:49'	System	27 Dec 2020 07:10:52

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-04T00:02:44', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5dee1cda-8b50-4e67-8718-8a9d984f8dc9'	System	04 Jan 2021 05:02:59
User entered 'No (N)'	System	04 Jan 2021 05:02:59

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-04T00:02:50', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5dee1cda-8b50-4e67-8718-8a9d984f8dc9'	System	04 Jan 2021 05:02:59
User entered 'No (N)'	System	04 Jan 2021 05:02:59



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-04T00:02:54', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '5dee1cda-8b50-4e67-8718-8a9d984f8dc9' User entered '04 Jan 2021 00:02:54'	System	04 Jan 2021 05:02:59
	System	04 Jan 2021 05:02:59

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-11T10:57:22', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'aea1ce5e-f1db-4d5f-92c0-6363accf8cb4'	System	11 Jan 2021 15:57:36
User entered 'No (N)'	System	11 Jan 2021 15:57:36

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-11T10:57:28', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'aea1ce5e-f1db-4d5f-92c0-6363accf8cb4'	System	11 Jan 2021 15:57:36
User entered 'No (N)'	System	11 Jan 2021 15:57:36

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-11T10:57:32', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'aea1ce5e-f1db-4d5f-92c0-6363accf8cb4'	System	11 Jan 2021 15:57:36
User entered '11 Jan 2021 10:57:32'	System	11 Jan 2021 15:57:36

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-17T06:49:33', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9393ac58-de9c-4aa2-9d85-9f89022a69f1'	System	17 Jan 2021 11:49:54
User entered 'No (N)'	System	17 Jan 2021 11:49:54

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-17T06:49:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9393ac58-de9c-4aa2-9d85-9f89022a69f1'	System	17 Jan 2021 11:49:54
User entered 'No (N)'	System	17 Jan 2021 11:49:54

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-17T06:49:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '9393ac58-de9c-4aa2-9d85-9f89022a69f1' User entered '17 Jan 2021 06:49:49'	System	17 Jan 2021 11:49:54

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-24T02:27:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f245e6f3-d41d-4106-8bb6-8ea3305ae06a'	System	24 Jan 2021 07:27:47
User entered 'No (N)'	System	24 Jan 2021 07:27:47

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-24T02:27:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f245e6f3-d41d-4106-8bb6-8ea3305ae06a'	System	24 Jan 2021 07:27:47
User entered 'No (N)'	System	24 Jan 2021 07:27:47

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-24T02:27:43', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'f245e6f3-d41d-4106-8bb6-8ea3305ae06a' User entered '24 Jan 2021 02:27:43'	System	24 Jan 2021 07:27:47

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-31T00:51:33', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'daf237b9-9b01-4320-a3f8-176ea31726bd'	System	31 Jan 2021 05:51:44
User entered 'No (N)'	System	31 Jan 2021 05:51:44

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-31T00:51:38', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'daf237b9-9b01-4320-a3f8-176ea31726bd'	System	31 Jan 2021 05:51:44
User entered 'No (N)'	System	31 Jan 2021 05:51:44



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-01-31T00:51:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'daf237b9-9b01-4320-a3f8-176ea31726bd' User entered '31 Jan 2021 00:51:41'	System	31 Jan 2021 05:51:44

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-07T00:40:34', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '48d03e0e-f169-4f1c-be39-3fb5a4567239'	System	07 Feb 2021 05:40:43
User entered 'No (N)'	System	07 Feb 2021 05:40:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-07T00:40:37', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '48d03e0e-f169-4f1c-be39-3fb5a4567239'	System	07 Feb 2021 05:40:43
User entered 'No (N)'	System	07 Feb 2021 05:40:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-07T00:40:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '48d03e0e-f169-4f1c-be39-3fb5a4567239'	System	07 Feb 2021 05:40:43
User entered '07 Feb 2021 00:40:40'	System	07 Feb 2021 05:40:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-14T00:10:11', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4f83e557-8dde-4610-b838-0d8e76ae45c4'	System	14 Feb 2021 05:10:30
User entered 'No (N)'	System	14 Feb 2021 05:10:30

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-14T00:10:20', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4f83e557-8dde-4610-b838-0d8e76ae45c4'	System	14 Feb 2021 05:10:30
User entered 'No (N)'	System	14 Feb 2021 05:10:30

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-14T00:10:26', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4f83e557-8dde-4610-b838-0d8e76ae45c4'	System	14 Feb 2021 05:10:30
User entered '14 Feb 2021 00:10:26'	System	14 Feb 2021 05:10:30

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-21T02:10:45', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a046145d-71b8-406b-8efb-fe2124727e87'	System	21 Feb 2021 07:10:57
User entered 'No (N)'	System	21 Feb 2021 07:10:57

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-21T02:10:49', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a046145d-71b8-406b-8efb-fe2124727e87'	System	21 Feb 2021 07:10:57
User entered 'No (N)'	System	21 Feb 2021 07:10:57

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-21T02:10:53', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'a046145d-71b8-406b-8efb-fe2124727e87'	System	21 Feb 2021 07:10:57
User entered '21 Feb 2021 02:10:53'	System	21 Feb 2021 07:10:57

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-28T00:46:16', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4ad6a2de-7ff6-4689-86cb-77affd41172b'	System	28 Feb 2021 05:46:51
User entered 'No (N)'	System	28 Feb 2021 05:46:51

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-28T00:46:41', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4ad6a2de-7ff6-4689-86cb-77affd41172b'	System	28 Feb 2021 05:46:51
User entered 'No (N)'	System	28 Feb 2021 05:46:51



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-28T00:46:47', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '4ad6a2de-7ff6-4689-86cb-77affd41172b'	System	28 Feb 2021 05:46:51
User entered '28 Feb 2021 00:46:47'	System	28 Feb 2021 05:46:51

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-08T17:41:12', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96fc325a-bc5f-431f-89e8-f28e94e5a669'	System	08 Mar 2021 22:41:24
User entered 'No (N)'	System	08 Mar 2021 22:41:24

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-08T17:41:16', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96fc325a-bc5f-431f-89e8-f28e94e5a669'	System	08 Mar 2021 22:41:24
User entered 'No (N)'	System	08 Mar 2021 22:41:24

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-08T17:41:19', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96fc325a-bc5f-431f-89e8-f28e94e5a669'	System	08 Mar 2021 22:41:24
User entered '08 Mar 2021 17:41:19'	System	08 Mar 2021 22:41:24

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-14T18:08:29', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'eec95bd2-ba9d-43c5-b581-d8df75f1b608'	System	14 Mar 2021 22:10:46
User entered 'No (N)'	System	14 Mar 2021 22:10:46

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-14T18:08:33', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'eec95bd2-ba9d-43c5-b581-d8df75f1b608'	System	14 Mar 2021 22:10:46
User entered 'No (N)'	System	14 Mar 2021 22:10:46

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-14T18:08:40', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'eec95bd2-ba9d-43c5-b581-d8df75f1b608'	System	14 Mar 2021 22:10:46
User entered '14 Mar 2021 18:08:40'	System	14 Mar 2021 22:10:46

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-25T09:10:24-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '429c8e4d-0c74-46ee-9b12-56d529df0519'	System	25 Mar 2021 13:10:38
User entered 'No (N)'	System	25 Mar 2021 13:10:38

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-25T09:10:30-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '429c8e4d-0c74-46ee-9b12-56d529df0519'	System	25 Mar 2021 13:10:38
User entered 'No (N)'	System	25 Mar 2021 13:10:38

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-25T09:10:34-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '429c8e4d-0c74-46ee-9b12-56d529df0519' User entered '25 Mar 2021 09:10:34'	System	25 Mar 2021 13:10:38
	System	25 Mar 2021 13:10:38

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-28T00:18:00-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '388b997b-755b-46b1-8565-aac96e271a3a'	System	28 Mar 2021 04:18:13
User entered 'No (N)'	System	28 Mar 2021 04:18:13

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-28T00:18:04-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '388b997b-755b-46b1-8565-aac96e271a3a'	System	28 Mar 2021 04:18:13
User entered 'No (N)'	System	28 Mar 2021 04:18:13



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-03-28T00:18:08-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '388b997b-755b-46b1-8565-aac96e271a3a'	System	28 Mar 2021 04:18:13
User entered '28 Mar 2021 00:18:08'	System	28 Mar 2021 04:18:13

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-05T08:56:32-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b9bd3e86-fe fd-4a37-9166-ca1c7d6026b6'	System	05 Apr 2021 12:56:41
User entered 'No (N)'	System	05 Apr 2021 12:56:41

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-05T08:56:34-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b9bd3e86-fe fd-4a37-9166-ca1c7d6026b6'	System	05 Apr 2021 12:56:41
User entered 'No (N)'	System	05 Apr 2021 12:56:41

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-05T08:56:38-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: 'b9bd3e86-fefd-4a37-9166-ca1c7d6026b6'	System	05 Apr 2021 12:56:41
User entered '05 Apr 2021 08:56:38'	System	05 Apr 2021 12:56:41

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-11T01:04:27-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '998ac385-fc22-4b25-bb7e-fe31b9595c2d'	System	11 Apr 2021 05:04:44
User entered 'No (N)'	System	11 Apr 2021 05:04:44

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-11T01:04:31-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '998ac385-fc22-4b25-bb7e-fe31b9595c2d'	System	11 Apr 2021 05:04:44
User entered 'No (N)'	System	11 Apr 2021 05:04:44

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-11T01:04:37-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '998ac385-fc22-4b25-bb7e-fe31b9595c2d' User entered '11 Apr 2021 01:04:37'	System	11 Apr 2021 05:04:44
	System	11 Apr 2021 05:04:44

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-19T10:00:11-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '1cba4e4c-b836-4ade-b585-92611a560006'	System	19 Apr 2021 14:00:43
User entered 'No (N)'	System	19 Apr 2021 14:00:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-19T10:00:28-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '1cba4e4c-b836-4ade-b585-92611a560006'	System	19 Apr 2021 14:00:43
User entered 'No (N)'	System	19 Apr 2021 14:00:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-19T10:00:39-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '1cba4e4c-b836-4ade-b585-92611a560006'	System	19 Apr 2021 14:00:43
User entered '19 Apr 2021 10:00:39'	System	19 Apr 2021 14:00:43

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-26T16:31:02-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96c73384-1703-4a11-8d6e-5d081da8c1b4'	System	26 Apr 2021 20:31:12
User entered 'No (N)'	System	26 Apr 2021 20:31:12

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-26T16:31:06-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96c73384-1703-4a11-8d6e-5d081da8c1b4'	System	26 Apr 2021 20:31:12
User entered 'No (N)'	System	26 Apr 2021 20:31:12



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-04-26T16:31:10-04:00', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '96c73384-1703-4a11-8d6e-5d081da8c1b4'	System	26 Apr 2021 20:31:12
User entered '26 Apr 2021 16:31:10'	System	26 Apr 2021 20:31:12

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:01:15



**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:01:15

**US3832014**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:59:05**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:01:15
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:01:15

US3832014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:05

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-28T00:46:01', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '009ab874-46cc-42bd-afde-daf7145bc14c'	System	28 Feb 2021 05:46:10
User entered 'No (N)'	System	28 Feb 2021 05:46:10

US3832014

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:59:05

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 20:31:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (28d2d8b6222b8d66)', Time: '2021-02-28T00:46:07', User OID: 'PatientReportedOutcome (US3832014)', ODM File OID: '009ab874-46cc-42bd-afde-daf7145bc14c'	System	28 Feb 2021 05:46:10
User entered '28 Feb 2021 00:46:07'	System	28 Feb 2021 05:46:10

**US3832014**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33

**US3832014**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '26 Oct 2020'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33



**US3832014**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33

US3832014

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:33

US3832014

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	26 Oct 2020 13:27:38

**US3832014**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 22:37:12
User entered 'I'	System	26 Oct 2020 13:27:38

**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:16

**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '24 Nov 2020'	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:16

**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:16

**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:16



**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	24 Nov 2020 19:54:21

**US3832014**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User entered 'I'	System	24 Nov 2020 19:54:21

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	29 Dec 2020 21:30:36

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '29 Dec 2020'	Ashten Sheriff (b) (4)	29 Dec 2020 21:30:36

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Ashten Sheriff (b) (4)	29 Dec 2020 21:30:36

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Ashten Sheriff (b) (4)	29 Dec 2020 21:30:36

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	29 Dec 2020 21:30:45

**US3832014**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User entered 'I'	System	29 Dec 2020 21:30:45



**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	25 Jan 2021 19:49:06

**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '25 Jan 2021'	Rodolfo Barrera (b) (4)	25 Jan 2021 19:49:06

**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	25 Jan 2021 19:49:06

**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Rodolfo Barrera (b) (4)	25 Jan 2021 19:49:06

**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	25 Jan 2021 19:49:12

**US3832014**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 15:51:49
User entered 'I'	System	25 Jan 2021 19:49:12

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:54:38

US3832014

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 13:12:36
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Correct as reported will be noted as a PD' (Site from System).	Danyel Johnson (b) (4) (b) (4)	24 Mar 2021 21:16:20
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Mar 2021 16:54:38
User entered '15 Mar 2021'	Rodolfo Barrera (b) (4) (b) (4)	23 Mar 2021 16:54:38



**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[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 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:54:38

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered 'VISIT4'	System	23 Mar 2021 16:54:38

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'No (N)'	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	(b) (4)	31 Mar 2021 02:32:07
	Danyel Johnson (b) (4)	
	(b) (4)	

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered empty.	System	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07



US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered empty.	System	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	(b) (4)	31 Mar 2021 02:32:07
	Danyel Johnson (b) (4)	
	(b) (4)	

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered empty.	System	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered empty.	System	31 Mar 2021 02:32:07

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	31 Mar 2021 02:32:07



US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered empty.	System	31 Mar 2021 02:32:07

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:59:05**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06

US3832014

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:59:05

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'No (N)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:55:30

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Rodolfo Barrera (b) (4)	23 Mar 2021 16:55:30

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:55:59

US3832014

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '15 Mar 2021'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:55:59

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '13:06'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:55:59



**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered '15 Mar 2021 13:06'	System	23 Mar 2021 16:55:59

US3832014

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:56:08

**US3832014**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:16:06
User entered 'I'	System	23 Mar 2021 16:56:08

**US3832014**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:57:54

**US3832014**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '23 Mar 2021'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:57:54

US3832014

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:59:05

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:57:54

**US3832014**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Rodolfo Barrera (b) (4)	23 Mar 2021 16:57:54

US3832014

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	23 Mar 2021 16:58:00



**US3832014**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:29:26
User entered 'I'	System	23 Mar 2021 16:58:00

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	03 Mar 2021 14:58:43

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:59:05

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '28 Jan 2021' reason for change: Data Entry Error	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	11 Mar 2021 19:58:47
	(b) (4)	
User entered '28 Feb 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	11 Mar 2021 19:58:34
User signature succeeded.	(b) (4)	
	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
	(b) (4)	
User entered '1 Feb 2021'	Rodolfo Barrera (b) (4)	03 Mar 2021 14:58:43
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	03 Mar 2021 14:58:43

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 14:58:43

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '28 Jan 2021'	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:00:20

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:59:05

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09
	(b) (4)	



**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:00:20

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:59:05

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '28 Jan 2021'	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:59:05

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Placebo (Placebo)'	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Placebo (Placebo)'	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:59:05

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Placebo (Placebo)'	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:59:05

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:47:09

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '1'	System	08 Feb 2021 19:47:09

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'I'	System	08 Feb 2021 19:47:09



US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered empty.	System	08 Feb 2021 19:54:49
DataPoint set to visible.	System	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered empty.	System	08 Feb 2021 19:54:49
DataPoint set to visible.	System	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User accepted default value 'Pre-Dose (PREDOSE)'	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49



US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1 Feb 2021'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '15:24'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '1 Feb 2021 15:24'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '98.1' F	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Oral (Oral)'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '84'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'bpm'	System	08 Feb 2021 19:54:49



US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '16'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'breaths/min'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '124'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '82'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered missing code ND - Not Done.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49



US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:59:05

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered empty.	System	08 Feb 2021 19:54:49
DataPoint set to visible.	System	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User accepted default value 'Post-Dose (POSTDOSE)'	Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '16:06'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '1 Feb 2021 16:06'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '98.1' F	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Oral (Oral)'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	



**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '72'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'bpm'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '18'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'breaths/min'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '102'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '71'	Danyel Johnson (b) (4)	08 Feb 2021 19:54:49



**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	08 Feb 2021 19:54:49

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:55:16

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:59:05

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User closed query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	11 Mar 2021 19:58:47
User opened query 'The Physical Examination Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	11 Mar 2021 19:58:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4)	08 Feb 2021 19:55:16
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mRNA-1273'	System	08 Feb 2021 19:56:03
DataPoint set to visible.	System	08 Feb 2021 19:47:09

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1 Feb 2021'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03



US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '15:35'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '1 Feb 2021 15:35'	System	08 Feb 2021 19:56:03

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Right Arm (RIGHT ARM)'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:03

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'ONCE'	System	08 Feb 2021 19:56:03

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'INTRAMUSCULAR'	System	08 Feb 2021 19:56:03

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:55

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	11 Mar 2021 19:58:47
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	03 Mar 2021 14:58:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '28 Jan 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	08 Feb 2021 19:56:55

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:59:05

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '14:55'	Danyel Johnson (b) (4)	08 Feb 2021 19:56:55



**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '28 Jan 2021 14:55'	System	08 Feb 2021 19:56:55

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:59:05**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	08 Feb 2021 19:57:15

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '28 Jan 2021'	Danyel Johnson (b) (4)	08 Feb 2021 19:57:15

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '14:47'	Danyel Johnson (b) (4)	08 Feb 2021 19:57:15

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:59:05**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '28 Jan 2021 14:47'	System	08 Feb 2021 19:57:15

US3832014

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	(b) (4)	
	Danyel Johnson (b) (4)	08 Feb 2021 19:57:22
	(b) (4)	

**US3832014**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'I'	System	08 Feb 2021 19:57:22

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Feb 2021 19:58:03



**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '8 Feb 2021'	Rodolfo Barrera (b) (4)	08 Feb 2021 19:58:03

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	08 Feb 2021 19:58:03

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Rodolfo Barrera (b) (4)	08 Feb 2021 19:58:03

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Feb 2021 19:58:10

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'I'	System	08 Feb 2021 19:58:10

**US3832014**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '1'	System	08 Feb 2021 19:58:10
DataPoint set to visible.	System	08 Feb 2021 19:58:10

**US3832014**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:11:22

**US3832014**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '15 Mar 2021'	Danyel Johnson (b) (4)	22 Mar 2021 14:11:22



**US3832014**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	22 Mar 2021 14:11:22

**US3832014**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:59:05**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'OLD29'	System	22 Mar 2021 14:11:22

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User accepted default value 'Pre-Dose (PREDOSE)'	Danyel Johnson (b) (4) (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '15 Mar 2021'	(b) (4)	
	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45
	(b) (4)	

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '13:17'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '15 Mar 2021 13:17'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '98.4' F	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45



US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Oral (Oral)'	(b) (4) Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '94'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'bpm'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '14'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'breaths/min'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '122'	(b) (4) Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	22 Mar 2021 14:15:45



US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '70'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User accepted default value 'Post-Dose (POSTDOSE)'	Danyel Johnson (b) (4) (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '15 Mar 2021'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '14:30'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '15 Mar 2021 14:30'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '98.7' F	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45



US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Oral (Oral)'	(b) (4) Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '94'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'bpm'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '14'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'breaths/min'	System	22 Mar 2021 14:15:45

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '127'	(b) (4)	
	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45
	(b) (4)	

US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	22 Mar 2021 14:15:45



US3832014

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:59:05

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '84'	Danyel Johnson (b) (4)	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mmHg'	System	22 Mar 2021 14:15:45

**US3832014**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'No (N)'	Danyel Johnson (b) (4)	22 Mar 2021 14:16:03

**US3832014**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:59:05**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:16:03

US3832014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

**US3832014**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

US3832014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

**US3832014**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'mRNA-1273'	System	22 Mar 2021 14:17:36
DataPoint set to visible.	System	08 Feb 2021 19:58:10



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Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '15 Mar 2021'	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

US3832014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '13:26'	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

**US3832014**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered '15 Mar 2021 13:26'	System	22 Mar 2021 14:17:36

US3832014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Right Arm (RIGHT ARM)'	Danyel Johnson (b) (4)	22 Mar 2021 14:17:36

US3832014

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:59:05

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'ONCE'	System	22 Mar 2021 14:17:36

**US3832014**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:59:05**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'INTRAMUSCULAR'	System	22 Mar 2021 14:17:36

US3832014

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:59:05

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	22 Mar 2021 14:17:44

**US3832014**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'I'	System	22 Mar 2021 14:17:44



**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	22 Mar 2021 16:27:59

**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered '22 Mar 2021'	Rodolfo Barrera (b) (4)	22 Mar 2021 16:27:59

**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	22 Mar 2021 16:27:59

**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:59:05**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered empty.	Rodolfo Barrera (b) (4)	22 Mar 2021 16:27:59

**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 22:59:12
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	22 Mar 2021 16:28:06

**US3832014**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:59:05**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:21:02
User entered 'I'	System	22 Mar 2021 16:28:06

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:59:05**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:43:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:08:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:00
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	20 Sep 2020 17:48:56



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 10:02:39
Query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' answered with 'Per review of medical records the Hypertension was linked to Pain ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	03 Dec 2020 15:59:04
User opened query 'Per DM CLR: Please review if this AE is a worsening of the recorded MH condition of Hypertension. If yes, please update to reflect the term worsening as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 02:14:52
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User closed query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:16:23
Query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' answered with 'Term updated ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	14 Oct 2020 17:08:49
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Accelerated and malignant hypertension, PT: Hypertensive emergency, LLT: Hypertensive emergency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:41:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 15:41:34
Data point term sent to Coder	System	14 Oct 2020 15:40:39
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	14 Oct 2020 15:40:22
User entered 'Hypertensive emergency' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Oct 2020 15:40:22

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: The subject's BP (220/151) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:37
Query 'PV Query: The subject's BP (220/1510) was in a range of hypertensive urgency. Please consider updating event term accordingly.' canceled (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:28
User opened query 'PV Query: The subject's BP (220/1510) was in a range of hypertensive urgency. Please consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:23
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:16:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Sep 2020 17:16:42
Data point term sent to Coder	System	18 Sep 2020 17:15:55
User entered 'Worsening of Hypertension'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:34:20
DataPoint Un-verified.		
	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
	(b) (4)	
User entered '31 Aug 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '14 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:15:27



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 18:34:23
DataPoint Un-verified.		
	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
	(b) (4)	
User entered '02 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	02 Nov 2020 15:58:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'I'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 14:55:28
Query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' answered with 'data updated per source' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	02 Nov 2020 15:58:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User opened query 'PV Query: Hospital admission and discharge dates are prior to the onset of the SAE. Please confirm if there are two separate hospitalizations and if so, please provide the details. If not, please reconcile and update the event onset and end dates. Otherwise, please clarify.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:31
User entered '31 Aug 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:03:39
User entered '14 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '02 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 14:03:39
	(b) (4)	
User entered '16 Sep 2020'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'No (N)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 17:15:59
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	18 Sep 2020 17:15:27
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 17:59:25
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' answered with 'Conmeds 9-19 are all associated with this event ' (Site from DM).	(b) (4), (b) (6) Danyel Johnson (b) (4) (b) (4)	27 Oct 2020 14:32:29 22 Oct 2020 11:42:06
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no ConMed record that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 02:04:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Sep 2020 17:15:59
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered '0'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User entered empty.	(b) (4), (b) (6)	18 Sep 2020 17:15:27



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatineine levels or indication of high or low.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 17:04:10
User closed query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 17:04:09
Query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatineine levels or indication of high or low.' answered with '1.30 was the reported level ref. range is 0.50-0.90' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:34:04
Query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' answered with 'Per subject report she suffers from COPD and Muscle spasms not Asthma and chronic pain' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:32:53
User closed query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:55:39
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)	03 Nov 2020 14:55:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' answered with 'Visit 0 B/P 128/83 7/31/2020 Visit 2 Day 29 B/P 163/93 8/28/2020 Visit 3 Day 57 B/P 162/100' (Site from Safety).	Danyel Johnson (b) (4)	02 Nov 2020 16:02:32
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 'Data has been added ' (Site from Safety).	Danyel Johnson (b) (4)	02 Nov 2020 15:59:32
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:29
User opened query 'PV Query: Per the discharge summary, "Her creatinine was slightly compared to 01 Sep 2020 due to probable dehydration from poor oral intake.", please provide creatineine levels or indication of high or low.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:54
User opened query 'PV Query: Per the discharge summary, the subject has a prior medical history of chronic pain and asthma. Please reconcile and update the medical history accordingly, if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:39
User opened query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 15:47:14
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)	23 Oct 2020 15:47:00

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:24
User closed query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:22
User closed query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:19
User closed query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:16
User closed query 'PV Query: Please clarify the reason for subject's emergency room visit.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:54:13
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)	16 Oct 2020 12:54:09
Query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' answered with 'Visit 0 B/P 128/83 7/31/2020 Visit 2 Day 29 B/P 163/93 8/28/2020 Visit 3 Day 57 B/P 162/100 ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:12:49
Query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' answered with 'Updated per review of hospital admission and discharge records, No report of shingles noted' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:07:29

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' answered with 'Updated per review of hospital admission and discharge records, No report of shingles noted' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:07:23
Query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' answered with 'Updated per review of hospital admission and discharge records ' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:06:41
Query 'PV Query: Please clarify the reason for subject's emergency room visit.' answered with 'Updated per review of hospital admission and discharge records ' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:06:36
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Updated per review of hospital admission and discharge records' (Site from Safety).	Danyel Johnson (b) (4)	15 Oct 2020 14:05:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Based on review of medical records received on 01 Oct 2020 the following information has been updated  Admission date 31 Aug 2020 Discharge date 02 Sep 2020 Admin Diagnosis Hypertensive Emergency  (Likely caused by acute back pain which resulted in hypertension, tachycardia and anxiety). 08/31/2020 Subject was seen in the ER early in the day for abdominal pain. The subject was treated with morphine for pain and had a CT scan of abdomen and pelvis which were both found to be within normal limits with no specific cause for pain. The subject later returned that day with severe headache and left upper quadrant abdominal pain. The subject was found on the bathroom floor. It is unclear how she ended up on the bathroom floor. Vitals obtained 08/31/2020 at 1402 by ER triage with the following findings: HR 113 B/P 242/136. Subject was admitted at this time point with nondescript abdominal pain, with noted negative x-ray and CT. Concern was noted that this episode may be representative of withdrawal since the subject has not been on her pain medication for the better part of the day. The subject remains confused and given the hypertensive emergency, stroke has been noted as a differential, but fortunately she has no acute unilateral deficits. Subject was admitted to ICU with the following plan: Hypertensive Emergency: Started on a Cardene drip and an Echo. Echo WNL Altered Mental Status: Stat CT of head WNL  Hyperglycemia: Monitor with collection of a HgA1c Elevated brain natriuretic peptide Level: Continue to monitor  Abdominal Pain: CT completed WNL with no acute pathology.  All collected information and comments have been updated.' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 14:05:04
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 12:16:33

PRODUCTION RELEASE (v12.003  
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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Sent via email 10/14/2020' (Site from Safety).	Danyel Johnson (b) (4)	14 Oct 2020 17:41:14
User opened query 'PV Query: The subject was reportedly found at ER with shingles. Please consider reporting AE/SAE Shingles.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:52
User opened query 'PV Query: The subject was reportedly found at ER with shingles. Please clarify confirmation of the diagnostic, extent and treatment.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:17:05
User opened query 'PV Query: As per the report, the subject was taking clonidine for 10 years. Please clarify the last several readings on BP (ie: prior to entry in the trial, at time of vaccination and at ER) and new BP medications at discharge.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 16:16:54
User opened query 'PV Query: At ER, BP was found to be 222/151. Please clarify whether the patient had clinical signs associated to the increased BP.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:56
User opened query 'PV Query: Please clarify the reason for subject's emergency room visit.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:41
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)	24 Sep 2020 15:41:29
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. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 15:41:10

US3832014

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
User entered 'At Day 50 safety call, subject reported being hospitalized from 14Sep2020 thru 16Sep2020 due to worsening of hypertension. Subject also reports AE of shingles. Subject states she went to ER on 14Sep2020 and was diagnosed with shingles. She reports her blood pressure was 222/151 mmHg. Subject reports being admitted to hospital for observation due to elevated blood pressure reading. She reports receiving several medications but is unable to recall the names at time of contact. Subject reports being discharged in stable condition on 16Sep2020. Subject was instructed to come to office as soon as possible to complete medical record release form. Will follow up upon receipt and review of medical records.'	(b) (4), (b) (6)	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 17:15:27



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Sep 2020 17:15:27

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'per hospital record discharge summary, subject had acute back pain which led to HTN crisis. please confirm if this should be captured as AE also and update as needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 14:17:31
Query 'per hospital record discharge summary, subject had acute back pain which led to HTN crisis. please confirm if this should be captured as AE also and update as needed.' answered with 'Data updated per record review' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	02 Dec 2020 21:07:54
User opened query 'per hospital record discharge summary, subject had acute back pain which led to HTN crisis. please confirm if this should be captured as AE also and update as needed.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:54:01
User coded data point as SOC: Psychiatric disorders, HLGT: 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)	15 Oct 2020 16:30:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:30:31
Data point term sent to Coder	System	15 Oct 2020 15:22:49
User entered 'Altered Mental status'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
User entered empty.	System	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '02 Sep 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
User entered empty.	System	15 Oct 2020 15:22:13

US3832014

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:11:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:44:34
User closed query 'Per source - gr 1 mild. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:44:14
Query 'Per source - gr 1 mild. Please reconcile. ' answered with 'Corrected per review' (Site from CRA).	Danyel Johnson (b) (4)	13 Apr 2021 20:33:51
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Apr 2021 20:33:35
Signature has been broken.	Danyel Johnson (b) (4)	13 Apr 2021 20:33:35
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Apr 2021 20:33:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User opened query 'Per source - gr 1 mild. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:04:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13



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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:22:13
User entered empty.	System	15 Oct 2020 15:22:13
	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

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Generated On: 10 Jun 2021 09:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:22:13
User entered empty.	System	15 Oct 2020 15:22:13
	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	15 Oct 2020 15:34:06
User opened query 'Data is required. Please complete.' (Site from System).	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
User entered empty.	(b) (4)	
	System	15 Oct 2020 15:22:13
	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	10 Nov 2020 17:36:43
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
	System	15 Oct 2020 15:34:06
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:22:13
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant 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) (4), (b) (6)	19 Nov 2020 15:16:10
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Reviewed and updated per source' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:37:57
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:36:43
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant 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)	06 Nov 2020 10:31:41
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:34:06
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:22:13



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Generated On: 10 Jun 2021 09:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:34:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:34:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Danyel Johnson (b) (4)	15 Oct 2020 15:34:06
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 15:22:13
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:04:28
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
User entered '0'	System	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33
User entered 'I'	System	15 Oct 2020 15:22:13

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:33

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Oct 2020 16:05:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:05:52
Data point term sent to Coder	System	15 Oct 2020 15:27:58
User entered 'Hyperglycemia'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
User entered empty.	System	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '2 Sep 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
User entered empty.	System	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:11:57
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 20:48:44
User closed query 'Per source - mild , gr 1. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:48:32
Query 'Per source - mild , gr 1. Please reconcile. ' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	13 Apr 2021 20:34:45
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	13 Apr 2021 20:34:26
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	13 Apr 2021 20:34:26
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 20:34:26
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User opened query 'Per source - mild , gr 1. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:06:20
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

US3832014

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:16:21
Query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'Reviewed and updated per source' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:38:37
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:38:22
User opened query 'Per DM CLR: Other Action Taken = None, however there is a Concomitant Medication (#11) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 10:32:09
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:34:26
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:34:26
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	15 Oct 2020 15:27:46
User entered '0'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 10 Jun 2021 09:59:05

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	10 Nov 2020 17:38:22
User entered '0'	(b) (4)	
	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46
	(b) (4)	

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:06:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
User entered '0'	System	15 Oct 2020 15:27:46



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42
User entered 'I'	System	15 Oct 2020 15:27:46

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:42

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Metabolism tests NEC, PT: Brain natriuretic peptide increased, LLT: Brain natriuretic peptide increased - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Oct 2020 16:27:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 16:27:26
Data point term sent to Coder	System	15 Oct 2020 15:33:09
User entered 'Elevated brain natriuretic peptide level'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
User entered empty.	System	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '02 Sep 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
User entered empty.	System	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:11:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:52:49
User closed query 'Per source - gr 1 imild. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:52:36
Query 'Per source - gr 1 imild. Please reconcile' answered with 'Reviewed and updated ' (Site from CRA).	Danyel Johnson (b) (4)	13 Apr 2021 20:35:54
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Apr 2021 20:35:37
Signature has been broken.	Danyel Johnson (b) (4)	13 Apr 2021 20:35:37
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Apr 2021 20:35:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User opened query 'Per source - gr 1 imild. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 19:08:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

US3832014

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:32:28
User entered empty.	System	15 Oct 2020 15:32:28
	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 10 Jun 2021 09:59:05

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:36:06
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Oct 2020 15:32:28
User entered empty.	System	15 Oct 2020 15:32:28
	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28
	(b) (4)	

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Generated On: 10 Jun 2021 09:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 15:36:06
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	System	15 Oct 2020 15:36:06
User opened query 'Data is required. Please complete.' (Site from System).	Danyel Johnson (b) (4)	15 Oct 2020 15:36:06
User entered empty.	(b) (4)	
	System	15 Oct 2020 15:32:28
	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28
	(b) (4)	

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'l'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28



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**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
User entered '0'	System	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44
User entered '1'	System	15 Oct 2020 15:32:28

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:44

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52

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Folder: Adverse Events

Form: Adverse Events (6)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:06:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 16:06:20
Data point term sent to Coder	System	15 Oct 2020 15:34:10
User entered 'Abdominal pain'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23



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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

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Form: Adverse Events (6)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
User entered empty.	System	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

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**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '02 Sep 2020'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
User entered empty.	System	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23
	(b) (4)	

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'I'	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

US3832014

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 10 Jun 2021 09:59:05

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant 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) (4), (b) (6)	19 Nov 2020 16:00:53
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'per log line 2 the data has been added' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	10 Nov 2020 17:40:50
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant 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)	06 Nov 2020 10:32:25
User entered 'I'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:08:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
User entered '0'	System	15 Oct 2020 15:33:23



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52
User entered 'I'	System	15 Oct 2020 15:33:23

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:52

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User closed query 'Acute back pain not listed in source. Please reconcile' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:53:45
Query 'Acute back pain not listed in source. Please reconcile' answered with 'Reviewed and updated in CIRO' (Site from CRA).	Danyel Johnson (b) (4)	13 Apr 2021 20:42:47
User opened query 'Acute back pain not listed in source. Please reconcile' (Site from CRA).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 19:15:53
	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Acute back pain - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Dec 2020 21:18:09
Data point term sent to Coder	(b) (4)	
User entered 'Acute back pain'	System	02 Dec 2020 21:16:16
	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User entered empty.	System	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '02 Sep 2020'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User entered empty.	System	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Grade 1/Mild (Grade 1/Mild)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

US3832014

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57



**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

US3832014

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#7 has a start date 31 Aug 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 17:58:15
Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#7 has a start date 31 Aug 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' answered with 'Updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Dec 2020 01:07:01
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	13 Dec 2020 01:06:50
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#7 has a start date 31 Aug 2020. Per page 35 of CCGs version 2.0, if an AE starts after dose 2, "action taken with investigational product" should be recorded as "Not Applicable". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Dec 2020 09:32:27
User entered 'None (NONE)'	Danyel Johnson (b) (4) (b) (4)	02 Dec 2020 21:15:57

US3832014

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
User entered '1' reason for change: Data Entry Error	System	02 Dec 2020 21:16:13
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	Danyel Johnson (b) (4)	02 Dec 2020 21:16:13
User entered '0'	(b) (4)	
	System	02 Dec 2020 21:15:57
	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57
	(b) (4)	

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57



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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 10 Jun 2021 09:59:05

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Dec 2020 21:16:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Danyel Johnson (b) (4)	02 Dec 2020 21:16:13
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Dec 2020 21:15:57
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	02 Dec 2020 21:15:57

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: SAE Narrative = TACHYCARDIA, AND ANXIETY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 15:14:18
Query 'Per DM CLR: SAE Narrative = TACHYCARDIA, AND ANXIETY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' answered with 'Reviewed and updated per chart review and subject report' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	25 Jan 2021 18:42:08
User opened query 'Per DM CLR: SAE Narrative = TACHYCARDIA, AND ANXIETY. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 03:18:21
User entered 'Noted in records reviewed for hypertensive emergency as the likely cause of hypertension, tachycardia, and anxiety'	Danyel Johnson (b) (4) (b) (4)	02 Dec 2020 21:15:57

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User entered '0'	System	02 Dec 2020 21:15:57

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57
User entered '0'	System	02 Dec 2020 21:15:57

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**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:12:57

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 19:06:51
User entered 'USA-US100-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	26 Jan 2021 19:06:46

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:59:05

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
User closed query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). 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) (4), (b) (6)	25 Feb 2021 12:11:50
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Sinus tachycardia, LLT: Sinus tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 20:53:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Feb 2021 20:53:07
Data point term sent to Coder	System	23 Feb 2021 20:37:30
Query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Updated per review' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:37:04
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:36:52
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:36:52
User entered 'SINUS TACHYCARDIA' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:36:52
User opened query 'Per DM CLR: Please specify the type of Tachycardia (e.g., Sinus Tachycardia, Ventricular Tachycardia). 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)	23 Feb 2021 04:24:46
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 16:55:53
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:46:52



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[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	25 Jan 2021 18:46:52
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	25 Jan 2021 18:46:04
User entered 'Tachycardia'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10
	(b) (4)	

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10



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**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '02 Sep 2020'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:59:05

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4) System	25 Jan 2021 18:45:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	25 Jan 2021 18:45:44
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	(b) (4) System	25 Jan 2021 18:45:27
User entered 'No (N)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Folder: Adverse Events

Form: Adverse Events (8)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	25 Jan 2021 18:45:27
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).		25 Jan 2021 18:45:27
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	25 Jan 2021 18:45:27
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	25 Jan 2021 18:45:10
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10
	(b) (4)	



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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:59:05

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	(b) (4)	25 Jan 2021 18:45:27
Query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' answered by data change (Site from System).	System	25 Jan 2021 18:45:27
User entered '02 Sep 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	25 Jan 2021 18:45:27
User opened query 'Hospital discharge date is prior to Hospital admission date. Please correct. ' (Site from System).	(b) (4)	25 Jan 2021 18:45:10
User entered '02 Aug 2020'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Form: Adverse Events (8)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'No (N)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Form: Adverse Events (8)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10



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**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:59:05

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#8 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' (Site from DM). Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#8 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 10:24:47
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	02 Feb 2021 16:53:33
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#8 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' (Site from DM). Query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#1 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' canceled (Site from DM).	Danyel Johnson (b) (4) (b) (4), (b) (6)	02 Feb 2021 16:53:26
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#1 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:44:09
User opened query 'Per CDM: Exposure Visit 2 Day 29 is recorded as 28 Aug 2020 and AE#1 has a start date 31 Aug 2020. Per page 46 of CCGs version 4.0, "Action taken with IP" should be recorded as "Not Applicable" IF an AE starts AFTER dose 2. Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 12:43:59
User entered 'None (NONE)'	(b) (4), (b) (6)	28 Jan 2021 12:42:47
	Danyel Johnson (b) (4) (b) (4)	25 Jan 2021 18:45:10

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User closed query 'Per DM RQ: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 14:20:13
Query 'Per DM RQ: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'Noted in ER records as a differential diagnosis no noted medication given for treatment.' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	25 Feb 2021 15:39:54
User opened query 'Per DM RQ: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:16:10
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 12:15:54
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'Per review of records no noted treatment ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	23 Feb 2021 20:37:28
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 04:25:02

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '1'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '0'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10

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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)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered empty.	Danyel Johnson (b) (4)	25 Jan 2021 18:45:10



US3832014

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 10 Jun 2021 09:59:05

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
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) (4), (b) (6)	04 Feb 2021 12:50:23
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 'per review COVID testing not completed' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	03 Feb 2021 16:48:30
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)	03 Feb 2021 14:45:26
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 18:46:34
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	25 Jan 2021 18:46:34
User entered 'NOTED IN RECORDS REVIEWED FOR HYPERTENSIVE EMERGENCY AS THE LIKELY CAUSE OF HYPERTENSION, TACHYCARDIA, AND ANXIETY' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	25 Jan 2021 18:46:34
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	25 Jan 2021 18:45:44
User entered empty.	Danyel Johnson (b) (4) (b) (4)	25 Jan 2021 18:45:10

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Jan 2021 18:45:44
User entered '0'	System	25 Jan 2021 18:45:10

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 18:45:10

**US3832014**

**Folder: Adverse Events**

**Form: Adverse Events (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Jan 2021 18:45:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:59:05

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:47:51
User closed query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 17:06:17
Query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' answered with 'Reviewed and added ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:40:35
User opened query 'Per ETRTR: Please add Medication and dosing provided for SAE Hypertensive Emergency, thanks.' (Site from CRA).	(b) (4), (b) (6)	24 Sep 2020 16:38:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:19:29

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: ANTICHOLINERGICS, PRODUCT: TIOTROPIUM BROMIDE, PRODUCTSYNONYM: SPIRIVA HANDIHALER - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 11:23:10
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 11:23:10
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 11:22:49
User entered 'Spiriva Handihaler'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'COPD- Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:22:05



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '5'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 12:51:43
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	06 Aug 2020 11:22:05
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:22:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:22:05

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:22:05

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:22:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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: COMBIVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:48:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Aug 2020 14:48:08
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 11:23:49
User entered 'Combivent'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '100/20'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:12:52
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	06 Aug 2020 11:23:31
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:23:31
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:23:31

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ANTIADRENERGIC AGENTS, CENTRALLY ACTING, ATC: IMIDAZOLINE RECEPTOR AGONISTS, PRODUCT: CLONIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:27:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Aug 2020 11:27:12
Data point term sent to Coder	System	06 Aug 2020 11:25:50
User entered 'Clonidine'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0.3'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:12:58
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	06 Aug 2020 11:25:14
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	24 Aug 2020 17:10:40
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	24 Aug 2020 17:10:40
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	06 Aug 2020 11:25:14
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:25:14
	(b) (4)	



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:25:14

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:25:14

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:25:14

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: LEVOSALBUTAMOL HYDROCHLORIDE, PRODUCTSYNONYM: XOPENEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 10:31:06
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 10:31:06
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 11:28:50
User entered 'Xopenex'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1.25'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:13:20
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	06 Aug 2020 11:28:05
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:28:05
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:28:05

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 08:30:48
Query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' answered with 'Flovent is an inhaled corticosteroid. Protocol prohibits systemic steroid use. Per Protocol Flovent is an allowable medication ' (Site from DM).	Danyel Johnson (b) (4)	23 Sep 2020 16:43:04
User opened query 'Per MM, Please review this medication and route. As per EC # 12 'Has received systemic immunosuppressants or immune-modifying drugs for >14 days in total within 6 months prior to Screening (for corticosteroids $\geq$ 20 mg/day of prednisone equivalent)'. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:05:59
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Aug 2020 23:26:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	07 Aug 2020 23:26:13
Data point term sent to Coder	System	06 Aug 2020 11:37:51
User entered 'Flovent'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Chronic Obstructive Pulmonary Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '88'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:11:56
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	06 Aug 2020 11:37:46
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:37:46
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:37:46

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Aug 2020 11:37:46

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:37:46

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:37:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Nov 2020 07:46:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 07:46:32
Data point term sent to Coder DataPoint Un-verified.	System Danyel Johnson (b) (4)	13 Nov 2020 13:29:46 13 Nov 2020 13:29:35
Coding entries removed.	(b) (4) Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
User entered 'HYDROMET 5 mg-1.5 mg/5 mL oral syrup [HYDROCODONE/HOMATROPINE]' reason for change: Per Query Resolution	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 13:29:35
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 17:32:49



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003. DataPoint Verified.	Coder Import (b) (4) (b) (4) (b) (4), (b) (6)	29 Oct 2020 17:32:49  27 Oct 2020 15:10:49
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:38:52 19 Oct 2020 18:38:32
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OPIUM ALKALOIDS AND DERIVATIVES, PRODUCT: HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE, PRODUCTSYNONYM: HYDROMET [HOMATROPINE METHYLBROMIDE;HYDROCODONE BITARTRATE] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:34:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:34:38
Data point term sent to Coder User closed query ' DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' (Site from System). Query '	System System  (b) (4), (b) (6)	24 Aug 2020 17:12:39 24 Aug 2020 17:12:26  24 Aug 2020 17:12:26
DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF. ' answered with 'data updated' (Site from System).		
User entered 'HYDROMET [hydrocodone/homatropine]' reason for change: Per Query Resolution	(b) (4), (b) (6)	24 Aug 2020 17:12:13
User opened query ' DM-Coding: Please add the active ingredient name(s) in brackets next to the drug name in the eCRF.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:59:10

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
' (Site from System).		
Data point term sent to Coder	System	06 Aug 2020 11:42:52
Data point term sent to Coder	System	06 Aug 2020 11:38:51
User entered 'Hydromet'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:10:51
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:10:57
User entered 'Chronic obstructive pulmonary disease'	Danyel Johnson (b) (4)	19 Oct 2020 18:38:32
reason for change: Data Entry Error	(b) (4)	
User entered 'Chronic cough'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per CDM RQ: Two drug component names were mentioned in the Name of medication, however the dose of only one drug component is entered in the Dose per administration. Please update the dose to include both components as applicable (e.g., 500/125). Thankyou.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 10:43:38
Query 'Per CDM RQ: Two drug component names were mentioned in the Name of medication, however the dose of only one drug component is entered in the Dose per administration. Please update the dose to include both components as applicable (e.g., 500/125). Thankyou.' answered with 'The drug is given in a 15ml dose data is correct as reported' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	29 Nov 2020 19:26:59
User opened query 'Per CDM RQ: Two drug component names were mentioned in the Name of medication, however the dose of only one drug component is entered in the Dose per administration. Please update the dose to include both components as applicable (e.g., 500/125). Thankyou.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:35:28
User closed query 'Per CDM re-query: Site response is noted; however, only one component of the drug has been noted. Please update the dose to include both components of HYDROMET 5 MG-1.5 MG/5 ML ORAL SYRUP. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 11:35:28
Query 'Per CDM re-query: Site response is noted; however, only one component of the drug has been noted. Please update the dose to include both components of HYDROMET 5 MG-1.5 MG/5 ML ORAL SYRUP. Thank you.' answered with 'The subject takes a total of 15ml and the dosages are listed in the medication field. Please advise what you want captured in the dose per administration field currently 15ml is listed which is the complete dose given' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	23 Nov 2020 16:19:49

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Site response is noted; however, only one component of the drug has been noted. Please update the dose to include both components of HYDROMET 5 MG-1.5 MG/5 ML ORAL SYRUP. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 16:57:13
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	20 Nov 2020 16:57:13
' (Site from DM).		
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	Danyel Johnson (b) (4)	13 Nov 2020 13:29:44
' answered with 'Reviewed and updated ' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User entered '15' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).	(b) (4), (b) (6)	13 Nov 2020 09:16:54
' (Site from DM).		
User closed query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:00:24
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:10:58
Query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Danyel Johnson (b) (4)	19 Oct 2020 18:36:17
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1.5' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:36:06
User opened query 'Per DM CLR: Please review the dose (1) of this medication as this is not the standard dose for this medication. This is typically in 1.5 MG. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 13:00:37
User entered '5/1'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User entered 'mL (mL)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 13:29:35
	(b) (4)	
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 18:00:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:12
	(b) (4)	
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4)	19 Oct 2020 18:36:24
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:36:06
	(b) (4)	
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:03:15
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'ug (ug)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:19
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:21
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'as needed (PRN)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:59:05**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:02
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	06 Aug 2020 11:41:56
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Aug 2020 11:41:56
User entered 'un UNK 2010' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:41:56
	(b) (4)	
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:38:07
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Aug 2020 11:41:56
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:41:56
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Aug 2020 11:38:07
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:38:07

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:38:07

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:27:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Sep 2020 10:27:42
	(b) (4)	
Data point term sent to Coder	System	18 Sep 2020 15:34:04
Coding entries removed.	Alyssa-Kay Peay (b) (4)	18 Sep 2020 15:33:10
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:44:09
	(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 16:44:09
	(b) (4)	
Data point term sent to Coder	System	06 Aug 2020 11:44:54
User entered 'Percocet'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User closed query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 16:45:55
Query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' answered with 'Updated per review of source ' (Site from DM).	Alyssa-Kay Peay (b) (4)	21 Sep 2020 11:49:25
User entered 'Chronic obstructive pulmonary disease' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 15:33:10
User opened query 'Per CDM: Indication is recorded as "Chest/Lung". Please update the indication of this medication to also include the medical condition/ diagnosis for the given organs.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 12:16:04
User entered 'Chest/Lung'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '7.5/325'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:09
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	06 Aug 2020 11:44:13
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:44:13
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Aug 2020 11:44:13

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 21:08:18
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 21:08:18
Data point term sent to Coder	System	06 Aug 2020 11:46:55
User entered 'Tizanidine'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Muscle spasms in the lower back'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '4'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'four times daily (QID)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
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.' canceled (Site from System).	(b) (4), (b) (6)	12 Aug 2020 15:12:28
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	06 Aug 2020 11:46:08
User entered 'un UNK 2013'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	06 Aug 2020 11:46:08
	(b) (4)	

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	06 Aug 2020 11:46:08

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Aug 2020 11:46:08



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Aug 2020 11:46:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:44:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:44:22
Data point term sent to Coder	System	19 Oct 2020 18:43:04
User entered 'Tylenol'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
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).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 16:53:14
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 'AE line #1 matched the time frame noted' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 13:31:36
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)	13 Nov 2020 09:17:12
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '650'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:42:32



US3832014

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User entered empty.	System	19 Oct 2020 18:42:32

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User entered empty.	System	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:06:46
User entered empty.	System	19 Oct 2020 18:42:32

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: ANTACIDS WITH ANTIFLATULENTS, PRODUCT: ALUMINIUM HYDROXIDE;MAGNESIUM HYDROXIDE;SIMETICONE, PRODUCTSYNONYM: MAALOX PLUS EXTRA STRENGTH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 18:12:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Jan 2021 18:12:29
Data point term sent to Coder	System	29 Nov 2020 19:30:14
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	29 Nov 2020 19:30:00
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Danyel Johnson (b) (4)	29 Nov 2020 19:30:00
DataPoint Un-verified.	Danyel Johnson (b) (4)	29 Nov 2020 19:29:46
User entered 'MAALOX PLUS(Dried Aluminium Hydroxide Gel ,Magnesium Hydroxide Simeticone, and sorbitol)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	29 Nov 2020 19:29:46

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System). DataPoint Verified.	Coder Import (b) (4) (b) (4)	24 Nov 2020 10:48:07
	(b) (4), (b) (6)	27 Oct 2020 15:11:42
Data point term sent to Coder	System	19 Oct 2020 18:55:37
Data point term sent to Coder	System	19 Oct 2020 18:44:11
User entered 'Maalox Plus'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	19 Oct 2020 18:55:32
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Reflux Prophylaxis' reason for change:	Danyel Johnson (b) (4)	19 Oct 2020 18:55:32
Data Entry Error	(b) (4)	
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of doses. Please verify the dose and unit, update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 11:13:46
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of doses. Please verify the dose and unit, update as appropriate. ' answered with 'Updated to 10ml's' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	02 Feb 2021 19:49:47
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	02 Feb 2021 19:49:26
User entered '10' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	02 Feb 2021 19:49:26
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than the number of doses. Please verify the dose and unit, update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 19:06:18
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:43:48



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	02 Feb 2021 19:49:26
	(b) (4)	
User entered 'mL (mL)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	02 Feb 2021 19:49:26
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Other (OTHER)'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	02 Feb 2021 19:49:26
User entered empty; reason for change Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	02 Feb 2021 19:49:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Dose'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48
	(b) (4)	

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:43:48

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:03:25
User entered empty.	System	19 Oct 2020 18:43:48

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, INTERMEDIATE- OR LONG-ACTING COMBINED WITH FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: ADMELOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:33:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 21:33:29
Data point term sent to Coder	System	19 Oct 2020 19:04:50
Data point term sent to Coder	System	19 Oct 2020 18:45:12
User entered 'Admelog'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hyperglycemia' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 19:04:41
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '1-10'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'IU (IU)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Subcutaneous (SUBCUTANEOUS)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:06

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User entered empty.	System	19 Oct 2020 18:45:06

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User entered empty.	System	19 Oct 2020 18:45:06

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:02
User entered empty.	System	19 Oct 2020 18:45:06



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM, PRODUCTSYNONYM: ATIVAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:13:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:13:27
Data point term sent to Coder	System	19 Oct 2020 18:46:15
User entered 'Ativan'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0.5'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:45:55

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User entered empty.	System	19 Oct 2020 18:45:55



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User entered empty.	System	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 11:39:29
User entered empty.	System	19 Oct 2020 18:45:55

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:16:36
Data point term sent to Coder	System	19 Oct 2020 18:47:16
User entered 'Melatonin'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '3'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:46:41

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User entered empty.	System	19 Oct 2020 18:46:41

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User entered empty.	System	19 Oct 2020 18:46:41

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:07
User entered empty.	System	19 Oct 2020 18:46:41

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:15:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:15:31
Data point term sent to Coder	System	19 Oct 2020 18:48:18
User entered 'Morphine Sulfate'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Abdominal Pain'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '2'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:48:08

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User entered empty.	System	19 Oct 2020 18:48:08

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User entered empty.	System	19 Oct 2020 18:48:08

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:04:37
User entered empty.	System	19 Oct 2020 18:48:08

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: NICARDIPINE HYDROCHLORIDE, PRODUCTSYNONYM: CARDENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:50:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:50:34
Data point term sent to Coder	System	19 Oct 2020 18:49:26
User entered 'Cardene'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Hypertensive Emergency'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:59:05**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '25'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'other (OTHER)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '5-15mg/hr'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:49:24

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User entered empty.	System	19 Oct 2020 18:49:24

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User entered empty.	System	19 Oct 2020 18:49:24

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:01:34
User entered empty.	System	19 Oct 2020 18:49:24



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 04:49:37
Data point term sent to Coder	System	19 Oct 2020 18:50:29
User entered 'Zofran'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Nausea Prophylaxis'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '4'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Intravenous (INTRAVENOUS)'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User entered empty.	System	19 Oct 2020 18:50:10



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User entered empty.	System	19 Oct 2020 18:50:10

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:07:14
User entered empty.	System	19 Oct 2020 18:50:10

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:08:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:08:32
Data point term sent to Coder	System	19 Oct 2020 18:51:31
User entered 'Percocet'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Abdominal Pain'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '7.5/325'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User entered empty.	System	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User entered empty.	System	19 Oct 2020 18:51:04

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:05
User entered empty.	System	19 Oct 2020 18:51:04

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 21:38:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
Data point term sent to Coder	System	19 Oct 2020 18:53:33
User entered 'Protonix'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Acid Reflux Prophylaxis'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '40'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'mg (mg)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:59:05

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User entered empty.	System	19 Oct 2020 18:52:40

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User entered empty.	System	19 Oct 2020 18:52:40

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:05:40
User entered empty.	System	19 Oct 2020 18:52:40

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 15:11:42
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: GLYCOLAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:03:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 22:03:47
Data point term sent to Coder	System	19 Oct 2020 18:54:36
User entered 'Glycolox'	Danyel Johnson (b) (4) (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11



US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'constipation Prophylaxis'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '17'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'g (g)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'once (ONCE)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:59:05**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered empty.	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11



**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:59:05**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '0'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:59:05**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered '01 Sep 2020'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:11:42
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Oct 2020 18:54:11

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:59:05**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User entered empty.	System	19 Oct 2020 18:54:11

**US3832014**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:59:05**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User entered empty.	System	19 Oct 2020 18:54:11

US3832014

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:59:05

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	22 Apr 2021 12:02:24
User entered empty.	System	19 Oct 2020 18:54:11



US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:59:05

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 15:23:57
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	15 Oct 2020 15:36:30

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:05

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:05:56
Query 'per source, also had abdominal x-ray. please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:18
User opened query 'per source, also had abdominal x-ray. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:40:46
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:37:51
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:06:00
Query 'per source, also had abdominal x-ray. please confirm and update' canceled (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:51
User opened query 'per source, also had abdominal x-ray. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:05:33
User entered 'Echocardiogram'	Danyel Johnson (b) (4)	15 Oct 2020 15:37:51
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:05:59
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:59:05

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:06:03
User entered empty.	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 15:37:51

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:09
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:10
User entered 'CT scan of pelvis and abdomen'	Danyel Johnson (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:12
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	15 Oct 2020 15:38:45



US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:59:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:34
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:13
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:38:45

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:05

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:24
User entered '31 Aug 2020'	Danyel Johnson (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:05

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:22
User entered 'CT Scan of head'	Danyel Johnson (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:05

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:21
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4)	15 Oct 2020 15:39:17

US3832014

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 09:59:05

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:26:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:06:19
User entered empty.	Danyel Johnson (b) (4)	15 Oct 2020 15:39:17

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '20/Sep/2020 13:49'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'I'	(b) (4), (b) (6)	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '15/Oct/2020 08:16'	System	15 Oct 2020 12:16:49



US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 12:54:46
User entered 'I'	(b) (4), (b) (6)	15 Oct 2020 12:16:49

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23



US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
User entered '16/Oct/2020 12:54'	System	16 Oct 2020 12:54:56

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	03 Nov 2020 14:56:25
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 12:54:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:04:10
User entered '03/Nov/2020 14:56'	System	03 Nov 2020 14:56:43

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 18:04:12
Reviewed for Safety.	(b) (4), (b) (6)	12 Nov 2020 17:06:49
User entered 'I'	(b) (4), (b) (6)	03 Nov 2020 14:56:43

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 18:04:22
User entered '12/Nov/2020 17:08'	System	12 Nov 2020 17:08:35

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	26 Jan 2021 19:07:04
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 18:04:23
User entered 'I'	(b) (4), (b) (6)	12 Nov 2020 17:08:35

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (6)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '26/Jan/2021 19:07'	(b) (4) System	26 Jan 2021 19:07:18



US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
Reviewed for Safety.	(b) (4), (b) (6)	03 Feb 2021 18:18:46
User entered '1'	(b) (4), (b) (6)	26 Jan 2021 19:07:18

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23



US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (7)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:16
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered '03/Feb/2021 13:18'	(b) (4) System	03 Feb 2021 18:19:02

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:16
Reviewed for Safety.	(b) (4), (b) (6)	24 Feb 2021 13:18:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 Feb 2021 18:19:02

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:32:52
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered	System	20 Sep 2020 17:48:56
'USA-US100-2020-MRNA-1273-P301000003'		

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:53
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:34:56
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Yes (Y)'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'No (N)'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Gowdhami'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Mohan'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '1655 E. Greenville St'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'Anderson'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered 'SC'	System	20 Sep 2020 17:48:56



**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	20 Sep 2020 17:49:17
User entered '29621'	System	20 Sep 2020 17:48:56

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:59:05**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 14:35:11
Reviewed for Safety.	(b) (4), (b) (6)	15 Oct 2020 12:16:41
User entered 'US'	System	20 Sep 2020 17:49:23

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 09:59:05

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
Signature has been broken.	System	24 Feb 2021 13:18:44
User entered '8'	System	24 Feb 2021 13:18:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 16:55:53
	(b) (4)	
User entered '7'	System	03 Feb 2021 18:19:02
User entered '6'	System	26 Jan 2021 19:07:18
User entered '5'	System	12 Nov 2020 17:08:35
User entered '4'	System	03 Nov 2020 14:56:43
User entered '3'	System	16 Oct 2020 12:54:56
User entered '2'	System	15 Oct 2020 12:16:49
User entered '1'	System	20 Sep 2020 17:49:23

**US3832014**

**Folder: SAE USA-US100-2020-MRNA-1273-P301000003**

**Form: Safety Report Form (8)**

**Generated On: 10 Jun 2021 09:59:05**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:15
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
User entered '24/Feb/2021 08:18'	(b) (4) System	24 Feb 2021 13:18:44

US3832014

Folder: SAE USA-US100-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 10 Jun 2021 09:59:05

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 19:09:15
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:04:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 13:18:44