

US3832176 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:58:54

All time stamps listed in this document are displayed in GMT

US3832176

Form: Participant Creation

Data signed: (b) (4) 21 Feb 2021 17:16:57

Generated On: 10 Jun 2021 09:58:54

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[Participant ID](#)

US3832176

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

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US3832176

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Date of Birth (MMM yyyy)	(b) (6) 1946
Age	74
Age Units	YEARS
Age (Derived)	74
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 14:20:25

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	12 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

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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 14:20:25

Generated On: 10 Jun 2021 09:58:54

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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) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	HIATAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832176

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	CATARACT (LEFT EYE)
Start date (dd MMM yyyy)	UN UNK 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 08 Mar 2021 12:10:32

Generated On: 10 Jun 2021 09:58:54

Condition	RIGHT SHOULDER INJURY
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	12 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	11:36 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:36
Height ( <i>xxx.x</i> )	165.1 cm
Weight ( <i>xxx.x</i> )	95.5 kg
BMI ( <i>xxx.x</i> )	35.03557 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 14:20:25

Generated On: 10 Jun 2021 09:58:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*) 12 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1998

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:20:25

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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 14:20:25

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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 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

What was the date of randomization? (dd MMM yyyy) 12 AUG 2020

What was the participant's randomization number? 185927

In what Cohort was the participant enrolled?   
 >=18 and <65 years and not at risk ☐   
 >=18 and <65 years and at risk ☐   
 >=65 years ☒

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☒ No ☐

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☐ No ☒

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

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 14:20:26

Generated On: 10 Jun 2021 09:58:54

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)	12 AUG 2020
Time of assessment (00:00-23:59)	11:36 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 11:36
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 14:20:26

Generated On: 10 Jun 2021 09:58:54

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)	12 AUG 2020
Time of assessment (00:00-23:59)	12:43 (24 HR)
Vital Signs Date and Time (derived)	12 AUG 2020 12:43
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)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 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 14:20:26

Generated On: 10 Jun 2021 09:58:54

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 14:20:25

Generated On: 10 Jun 2021 09:58:54

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 12 AUG 2020

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

Treatment Date and Time (derived) 12 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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 AUG 2020
Collection time (00:00-23:59)	12:02 (24 HR)
Collection date and time (derived)	12 AUG 2020 12:02



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

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 09:58:54

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**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

98.3 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 AUG 2020 12:43

---

PC Open Date & Time

12 AUG 2020 12:33

---

PC Close Date & Time

12 AUG 2020 15:03

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**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 98.2 °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	12 AUG 2020 16:19
PC Open Date & Time	12 AUG 2020 15:58
PC Close Date & Time	13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**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

98.2 °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

13 AUG 2020 21:40

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 14:48

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:14

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:55

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 18 AUG 2020 07:57

PC Open Date & Time 17 AUG 2020 12:00

PC Close Date & Time 18 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 11:24

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 12:43

PC Open Date & Time

12 AUG 2020 12:33

PC Close Date & Time

12 AUG 2020 15:03

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 16:20

PC Open Date & Time

12 AUG 2020 15:58

PC Close Date & Time

13 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**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

13 AUG 2020 21:41

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 14:49

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:55

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**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

18 AUG 2020 07:57

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**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

19 AUG 2020 11:24

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**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 ☐

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 12:44
PC Open Date & Time	12 AUG 2020 12:33
PC Close Date & Time	12 AUG 2020 15:03

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**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 ☐

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

No ☒

Yes ☐

PC Time stamp	12 AUG 2020 16:21
PC Open Date & Time	12 AUG 2020 15:58
PC Close Date & Time	13 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:41
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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

56 of 2440

EAB) (1725)

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 14:49
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**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  
EAB) (1725)

58 of 2440

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:15
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2440

EAB) (1725)

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:57
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2440

EAB) (1725)

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 07:58
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 ☒

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 11:24
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3832176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	11:18 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 11:18
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

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)	09 SEP 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 12:16
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 11:40 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 11:40

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

What was the frequency of the study treatment dosing? ONCE

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

US3832176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 SEP 2020

Collection time (00:00-23:59)

11:31 (24 HR)

Collection date and time (derived)

9 SEP 2020 11:31

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:26	09 SEP 2020 11:26
Nasopharyngeal Swab 2	No		

US3832176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

09 SEP 2020 12:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 14:30

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °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 09 SEP 2020 20:42

PC Open Date & Time 09 SEP 2020 15:25

PC Close Date & Time 10 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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**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

98.2 °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

10 SEP 2020 21:08

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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

11 SEP 2020 17:23

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 19:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °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

13 SEP 2020 23:09

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 01:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 09:06

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:19

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 14:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**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

09 SEP 2020 20:43

PC Open Date & Time

09 SEP 2020 15:25

PC Close Date & Time

10 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**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

10 SEP 2020 21:08

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**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

11 SEP 2020 17:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**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

12 SEP 2020 19:53

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**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

13 SEP 2020 23:09

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**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

15 SEP 2020 01:45

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**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

16 SEP 2020 09:06

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**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 ☐

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 12:20
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 14:30

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**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 ☐

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 20:43
PC Open Date & Time	09 SEP 2020 15:25
PC Close Date & Time	10 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 21:09
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 ☒

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 17:25
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 ☒

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 19:54
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 23:10
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 ☒

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 01:46
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 09:06
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59



US3832176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:25

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	7 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	11:12 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 11:12
Temperature ( <i>xxx.x</i> )	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	70 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	68 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3832176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3832176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 OCT 2020

Collection time (00:00-23:59)

11:22 (24 HR)

Collection date and time (derived)

7 OCT 2020 11:22

US3832176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:20:26

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

13 OCT 2020 13:03:28

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 OCT 2020 16:53:02

Patient Cloud Open Date & Time

19 OCT 2020 00:01

Patient Cloud Close Date & Time

23 OCT 2020 23:59

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

27 OCT 2020 19:12:34

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

09 NOV 2020 14:25:50

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 09:56:39
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 16:01:51

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 15:51:19

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

04 DEC 2020 11:44:41

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 10:22:41

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

18 DEC 2020 14:52:39

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

25 DEC 2020 16:27:11

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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)	True
Chills	True
Cough	True
Shortness of breath	True
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

01 JAN 2021 08:15:22

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

11 JAN 2021 10:34:38

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

17 JAN 2021 16:04:35

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

23 JAN 2021 08:22:33

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

29 JAN 2021 16:41:14

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

05 FEB 2021 14:09:18

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 11:14:33

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

<b>TIMEPOINT</b>	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	19 FEB 2021 13:03:50
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 02:08:40

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 MAR 2021 18:51:17
Patient Cloud Open Date & Time	12 MAR 2021 00:01
Patient Cloud Close Date & Time	16 MAR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 MAR 2021 19:45:32
Patient Cloud Open Date & Time	19 MAR 2021 00:01
Patient Cloud Close Date & Time	23 MAR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

29 MAR 2021 14:06:40

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

02 APR 2021 14:21:08

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

09 APR 2021 09:30:20

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

16 APR 2021 18:19:32

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 12:10:53
Patient Cloud Open Date & Time	23 APR 2021 00:01
Patient Cloud Close Date & Time	27 APR 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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

30 APR 2021 16:20:54

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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07 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 MAY 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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14 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 MAY 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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21 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 MAY 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐ 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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	13 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	17 AUG 2021 23:59
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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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27 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 AUG 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

10 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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08 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 OCT 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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05 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 NOV 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	19 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 NOV 2021 23:59
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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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26 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 NOV 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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="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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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°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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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31 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JAN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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04 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 FEB 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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04 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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22 MAR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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29 MAR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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19 APR 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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29 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAY 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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17 MAY 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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27 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAY 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

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07 JUN 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

10 JUN 2022 00:01

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14 JUN 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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24 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUN 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐  
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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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05 JUL 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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26 JUL 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2022 23:59
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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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°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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

09 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59



US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**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 ☐

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

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[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

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US3832176

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2022 23:59

US3832176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:58:54

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		01 MAR 2021 02:08:58

US3832176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3832176

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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*

US3832176

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

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) \_\_\_\_\_

US3832176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

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.*

US3832176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

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

Collection date (dd MMM yyyy)	08 APR 2021
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Collection time (00:00-23:59)	10:41 (24 HR)
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Collection date and time (derived)	08 APR 2021 10:41
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US3832176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3832176**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

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*

**US3832176**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3832176

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:58:54

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"/>

**US3832176**

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

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

**Generated On: 10 Jun 2021 09:58:54**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3832176

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3832176

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:12:54

Generated On: 10 Jun 2021 09:58:54

Date of updated informed consent ( <i>dd MMM yyyy</i> )	4 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> )	4 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



US3832176

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

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

US3832176

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

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)	4 JAN 2021
Time of assessment (00:00-23:59)	14:04 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 14:04
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)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

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)	4 JAN 2021
Time of assessment (00:00-23:59)	14:56 (24 HR)
Vital Signs Date and Time (derived)	4 JAN 2021 14:56
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 JAN 2021

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

US3832176

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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) 4 JAN 2021

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

Treatment Date and Time (derived) 4 JAN 2021 14:23

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

US3832176

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

4 JAN 2021

Collection time (00:00-23:59)

13:46 (24 HR)

Collection date and time (derived)

4 JAN 2021 13:46

US3832176

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 JAN 2021
Collection time (00:00 - 23:59)	13:40
Collection Date and Time (derived)	4 JAN 2021 13:40

US3832176

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3832176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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

US3832176

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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)	14:08 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 14:08
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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)	14:51 (24 HR)
Vital Signs Date and Time (derived)	1 FEB 2021 14:51
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3832176

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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.*

US3832176

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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) 14:17 (24 HR)

Treatment Date and Time (derived) 1 FEB 2021 14:17

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

US3832176

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3832176

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

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*

US3832176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3832176

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 29 Apr 2021 02:21:28

Generated On: 10 Jun 2021 09:58:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 29 Apr 2021 02:21:28

Generated On: 10 Jun 2021 09:58:54

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) \_\_\_\_\_

US3832176

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 29 Apr 2021 02:21:28

Generated On: 10 Jun 2021 09:58:54

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 29 Apr 2021 02:21:28

Generated On: 10 Jun 2021 09:58:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	10:41 (24 HR)
Collection date and time (derived)	8 APR 2021 10:41

US3832176

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 18:39:51

Generated On: 10 Jun 2021 09:58:54

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3832176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

AEID	USA-US100-2021-MRNA-1273-P30 1000011
Adverse event	WORSENING OF PARAOESOPHAGEAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	03 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

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	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3832176

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

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75 Y/O FEMALE VACCINATED  
1/4/2021 LAST DOSE OF IP  
2/1/2021 WITH A HISTORY OF  
HYPERTENSION,  
PARAOESOPHAGEAL HERNIA,  
BREAST CANCER  
(LUMPECTOMY AND  
RADIATION) WAS SEEN ON  
3/2/2021 AT THE EMERGENCY  
ROOM IN (b) (6) AND ADMITTED  
WHILE VISITING HER  
DAUGHTER AFTER  
EXPERIENCING SEVER  
ABDOMINAL PAIN WITH  
NAUSEA AND VOMITING THAT  
STARTED 3/1/2021 AROUND  
1830. SUBJECT HAD A CT SCAN  
WHICH SHOWED A LARGE  
TYPE 4 PARAOESOPHAGEAL  
HERNIA WITH MOST OF THE  
STOMACH IN THE CHEST ON  
THE LEFT SIDE AND A PORTION  
OF THE TRANSVERSE COLON.  
DUODENUM WAS NOTED TO  
PULLED UP ALSO INTO THE  
PORTION OF THE HERNIA. NO  
NOTED ISCHEMIA ON CT SCAN.  
SUBJECT WAS SCHEDULED FOR  
A ROBOTIC ASSISTED  
PARAOESOPHAGEAL HERNIA  
REPAIR WITH NISSEN  
FUNDOPLICATION ON 3/3/2021.  
SUBJECT REMAINED IN THE  
HOSPITAL UNTIL 3/8/2021 FOR  
POST-OPERATIVE CARE.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3832176

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

AEID	
Adverse event	ATRIAL FIBRILLATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

AEID	USA-US100-2021-MRNA-1273-P30 1000012
Adverse event	VERTIGO
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)	22 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 APR 2021
Hospital Discharge Date (dd MMM yyyy)	25 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

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 type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 29 Apr 2021 18:40:42

Generated On: 10 Jun 2021 09:58:54

---

SUBJECT CONTACTED AFTER  
HER DIARY INDICATED A  
CHANGE IN HEALTH STATUS.  
PER SUBJECT SHE WAS  
ADMITTED 4/23/2021 AFTER  
EXPERIENCING VERTIGO  
SUBJECT WAS DISCHARGED  
4/25/2021 WITH ANTIVERT 25MG  
PRN. RECORDS RELEASE SENT  
TO SUBJECT TO OBTAIN ALL  
INFORMATION FOR COURSE OF  
TREATMENT WHILE  
HOSPITALIZED.

---

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)	

---

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US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

---

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

Yes ☒

No ☐

---

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

---



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication PANTOTRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2000
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) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 2.5

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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US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication LEXAPRO

Prophylaxis Yes ☐  
No ☒

Indication INSOMNIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication CILOSTAZOL

Prophylaxis Yes ☐  
No ☒

Indication PERIPHERAL ARTERIAL DISEASE

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2018
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (7)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication FAMOTIDINE

Prophylaxis Yes ☒  
No ☐

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2000
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 (9)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication GENERAL MYALGIA

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 2011	
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 (10)

Data signed: (b) (4) 03 May 2021 18:40:07

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Name of Medication PREDNISONE 1%

Prophylaxis Yes ☒  
No ☐

Indication LEFT EYE POST CATARACT  
SURGERY INFECTION  
PREVENTIVE

Dose per administration 1

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

If dose unit is Other, specify DROP

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 (10)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	Intraocular	<input checked="" 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)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 18:40:07

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLACTIC

Dose per administration .5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 18:40:07

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	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		07 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 18:40:07

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Name of Medication MECLIZINE

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 1970	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:40:07

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Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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 1970	
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 (14)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication BROMFENAC OPHTHALMIC  
SOLUTION 0.075%

Prophylaxis Yes ☒  
No ☐

Indication POST CATARACT SURGERY  
INFECTION PREVENTIVE

Dose per administration 1

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

If dose unit is Other, specify DROP

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 (14)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	Intraocular	<input checked="" 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)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	10 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication BROMFENAC 0.075%

Prophylaxis Yes ☒  
No ☐

Indication POST CATARACT SURGERY  
INFECTION PREVENTIVE

Dose per administration 1

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

If dose unit is Other, specify DROPS

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 (15)

Data signed: (b) (4) 03 May 2021 18:40:07

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	Intraocular	<input checked="" 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)		31 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication ELIQUIS

Prophylaxis Yes ☐  
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

390 of 2440

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

Name of Medication ANTIVERT

Prophylaxis Yes ☐  
No ☒

Indication VERTIGO

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

392 of 2440

EAB) (1725)

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

	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)	22 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 17:16:58

Generated On: 10 Jun 2021 09:58:54

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 22:12:59

Generated On: 10 Jun 2021 09:58:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
31 AUG 2020	CATARACT SURGERY - LEFT EYE	Medical History	
03 MAR 2021	ROBOTIC ASSISTED PARAOESOPHAGEAL HERNIA REPAIR	Adverse Event	

US3832176

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:58:54

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3832176

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:58:54

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 ☐

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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)	3

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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)	3
Date of submission (Pre-filled from custom function)	13/APR/2021 09:50
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



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 09:30
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

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000011
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input 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)	3
Date of submission (Pre-filled from custom function)	03/MAY/2021 12:13
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

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000012
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)	2

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000012
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)	2
Date of submission (Pre-filled from custom function)	27/APR/2021 10:28
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

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 18:40:07

Generated On: 10 Jun 2021 09:58:54

SAEID	USA-US100-2021-MRNA-1273-P301000012
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)	2
Date of submission (Pre-filled from custom function)	29/APR/2021 15:21
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

US3832176 (Prod: Keystone VitaLink Research - Anderson - PPDS)

**US3832176**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:58:54**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 16:34:39
User entered 'US3832176'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:24:31

US3832176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:01
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:37



US3832176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:40:01
User entered '12 AUG 2020'	RWS_ENDPOINT	12 Aug 2020 15:24:32
	ENDPOINT (b) (4)	

US3832176

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:01
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:37

**US3832176**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'SCRN'	System	12 Aug 2020 15:28:37

US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered (b) (6) 1946'	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:24:33

US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '74'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'YEARS'	System	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '74'	System	12 Aug 2020 15:29:01

US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered 'Female (F)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51



US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered 'l'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

US3832176

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:58:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51



**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

**US3832176**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:58:54**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:19
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:28:51

US3832176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01

**US3832176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Aug 2020'	System	12 Aug 2020 15:29:01

**US3832176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2020'	System	12 Aug 2020 15:29:01

US3832176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered 'Amendment 2 (2)' reason for change: New Information	Alyssa-Kay Peay (b) (4)	13 Aug 2020 11:07:00
User entered 'Amendment 1 (1)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01



US3832176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01

**US3832176**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:58:54**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:01

US3832176

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:40:25
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:24:32

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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:58:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'I'	System	12 Aug 2020 15:29:22

US3832176

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:03
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:22

US3832176

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:58:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:42:09
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:29

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:31:16
Data point term sent to Coder	System	12 Aug 2020 15:30:19
User entered 'Hiatal Hernia'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:29:44

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'un UNK 2000'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:44



**US3832176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:44

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:44

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:44

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:29:44

**US3832176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2000'	System	12 Aug 2020 15:29:44

US3832176

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2000'	System	12 Aug 2020 15:29:44

**US3832176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:29:44

**US3832176**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:29:44



US3832176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
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)	12 Aug 2020 15:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:31:16
Data point term sent to Coder	System	12 Aug 2020 15:30:20
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:30:02

US3832176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'un UNK 1995'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:02

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:02

**US3832176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:02

US3832176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:02

US3832176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:02

**US3832176**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 1995'	System	12 Aug 2020 15:30:02

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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '1995'	System	12 Aug 2020 15:30:02



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Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:30:02

US3832176

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:30:02

US3832176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:31:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:31:15
Data point term sent to Coder	System	12 Aug 2020 15:30:24
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:30:12

US3832176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:12

US3832176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:12

US3832176

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:12

**US3832176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:12

**US3832176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:12



**US3832176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2015'	System	12 Aug 2020 15:30:12

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Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2015'	System	12 Aug 2020 15:30:12

**US3832176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:30:12

**US3832176**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	12 Aug 2020 15:30:12

US3832176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:32:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 15:32:21
Data point term sent to Coder	System	12 Aug 2020 15:31:25
User entered 'Breast Cancer'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:30:28

US3832176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:28

**US3832176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:28

**US3832176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:28



US3832176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:52
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 17:35:31
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 17:35:31
User entered 'UN UNK 2014' reason for change:	(b) (4)	
Data Entry Error	Danyel Johnson (b) (4)	24 Feb 2021 17:35:31
User signature succeeded.	(b) (4)	
	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'un UNK 2015'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:28
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:28

**US3832176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2014'	System	12 Aug 2020 15:30:28

US3832176

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2014'	System	12 Aug 2020 15:30:28

**US3832176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2014'	System	24 Feb 2021 17:35:31
User entered 'Jan 2015'	System	12 Aug 2020 15:30:28

**US3832176**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2014'	System	24 Feb 2021 17:35:31
User entered '2015'	System	12 Aug 2020 15:30:28

US3832176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:21:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:21:55
Data point term sent to Coder	System	07 Oct 2020 15:17:41
User entered 'Seasonal Allergies'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'UN UNK 1970'	Ashten Sheriff (b) (4)	07 Oct 2020 15:16:52



US3832176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Ashten Sheriff (b) (4)	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Ashten Sheriff (b) (4)	07 Oct 2020 15:16:52

US3832176

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Ashten Sheriff (b) (4)	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Ashten Sheriff (b) (4)	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 1970'	System	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '1970'	System	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	07 Oct 2020 15:16:52

**US3832176**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	07 Oct 2020 15:16:52



US3832176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 12:48:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 12:48:30
Data point term sent to Coder	System	20 Oct 2020 12:48:13
User entered 'Post Menopausal'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Oct 2020 12:47:50

US3832176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User closed query 'Per DM CLR: Please note, Start date of MH = UN UNK 1998. However, Post-menopausal date recorded in Childbearing ecf is unknown. Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 17:15:22
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:20:26
Query 'Per DM CLR: Please note, Start date of MH = UN UNK 1998. However, Post-menopausal date recorded in Childbearing ecf is unknown. Review and reconcile dates as appropriate. Else, clarify. ' answered with 'childbearing ecf updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:53:07
User opened query 'Per DM CLR: Please note, Start date of MH = UN UNK 1998. However, Post-menopausal date recorded in Childbearing ecf is unknown. Review and reconcile dates as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 02:15:24
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'UN UNK 1998'	Alyssa-Kay Peay (b) (4) (b) (4)	20 Oct 2020 12:47:50

**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 12:47:50

**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 12:47:50

US3832176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	20 Oct 2020 12:47:50

**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	20 Oct 2020 12:47:50

US3832176

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:58:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 1998'	System	20 Oct 2020 12:47:50

**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '1998'	System	20 Oct 2020 12:47:50



**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	20 Oct 2020 12:47:50

**US3832176**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	20 Oct 2020 12:47:50

US3832176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:58:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:01:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:01:47
Data point term sent to Coder	System	22 Oct 2020 20:00:15
User entered 'Gastroesophageal Reflux Disease'	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 19:59:40

US3832176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'UN UNK 2019'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 19:59:40



US3832176

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2019'	System	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2019'	System	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	22 Oct 2020 19:59:40

**US3832176**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	22 Oct 2020 19:59:40

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:16:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:16:34
Data point term sent to Coder	System	22 Oct 2020 20:15:40
User entered 'General Myalgia'	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'per source, 2011. please confirm and update.' (Site from CRA).	(b) (4)	10 Dec 2020 18:49:31
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 18:49:29
Query 'per source, 2011. please confirm and update.' answered with 'Verified and updated' (Site from CRA).	Danyel Johnson (b) (4)	07 Dec 2020 20:59:44
User entered 'UN UNK 2011' reason for change:	Danyel Johnson (b) (4)	07 Dec 2020 20:59:36
Data Entry Error	(b) (4)	
User opened query 'per source, 2011. please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:23:42
DataPoint Un-verified.	(b) (4), (b) (6)	24 Nov 2020 18:23:23
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'UN UNK 2019'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:15:02



**US3832176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered empty.	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:15:02

**US3832176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2011'	System	07 Dec 2020 20:59:36
User entered 'Jan 2019'	System	22 Oct 2020 20:15:02

**US3832176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2011'	System	07 Dec 2020 20:59:36
User entered '2019'	System	22 Oct 2020 20:15:02

**US3832176**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	22 Oct 2020 20:15:02

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:07
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataract (left) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:24:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:24:39
Data point term sent to Coder	System	22 Oct 2020 20:23:58
User entered 'Cataract (left eye)'	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:23:40

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'UN UNK 2020'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:23:40



US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:23:40

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 18:49:44
User closed query 'surgery did not occur until after randomization. please confirm Yes and update as needed.' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 18:49:41
Query 'surgery did not occur until after randomization. please confirm Yes and update as needed.' answered with 'updated' (Site from CRA).	Danyel Johnson (b) (4)	07 Dec 2020 21:01:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	07 Dec 2020 21:01:07
User opened query 'surgery did not occur until after randomization. please confirm Yes and update as needed.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 19:33:44
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 19:32:54
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:23:40

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'please delete date' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 18:49:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 18:49:48
Query 'please delete date' answered with 'UPdated' (Site from CRA).	Danyel Johnson (b) (4)	07 Dec 2020 21:01:23
	(b) (4)	
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	07 Dec 2020 21:01:07
	(b) (4)	
User opened query 'please delete date' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 19:33:40
DataPoint Un-verified.	(b) (4), (b) (6)	20 Nov 2020 19:32:49
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '31 Aug 2020'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:23:40
	(b) (4)	

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:07
User entered '0'	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:23:40

US3832176

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2020'	System	22 Oct 2020 20:23:40

**US3832176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2020'	System	22 Oct 2020 20:23:40

**US3832176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	07 Dec 2020 21:01:07
User entered 'Aug 2020'	System	22 Oct 2020 20:23:40

**US3832176**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	07 Dec 2020 21:01:07
User entered '2020'	System	22 Oct 2020 20:23:40



US3832176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Peripheral vasoconstriction, necrosis and vascular insufficiency, PT: Peripheral arterial occlusive disease, LLT: Peripheral arterial disease - 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)	05 Feb 2021 14:57:43
Data point term sent to Coder	(b) (4)	
User entered 'PERIPHERAL ARTERIAL DISEASE'	System	05 Feb 2021 14:57:00
	Danyel Johnson (b) (4)	05 Feb 2021 14:56:35
	(b) (4)	

US3832176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered 'UN UNK 2018' reason for change: Data Entry Error	System	05 Feb 2021 14:56:45
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Danyel Johnson (b) (4)	05 Feb 2021 14:56:45
User entered ' UNK 2018' (non-conformant).	(b) (4)	
	System	05 Feb 2021 14:56:35
	Danyel Johnson (b) (4)	05 Feb 2021 14:56:35
	(b) (4)	

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:56:35

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:56:35

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:56:35

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:56:35

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2018'	System	05 Feb 2021 14:56:45
User entered empty.	System	05 Feb 2021 14:56:35

**US3832176**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2018'	System	05 Feb 2021 14:56:45
User entered empty.	System	05 Feb 2021 14:56:35



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Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	05 Feb 2021 14:56:35

US3832176

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	05 Feb 2021 14:56:35

US3832176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - 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)	24 Feb 2021 17:31:01
Data point term sent to Coder	(b) (4)	
User entered 'Bilateral knee osteoarthritis'	Coder Import (b) (4)	24 Feb 2021 17:31:01
	(b) (4)	
	System	24 Feb 2021 17:29:33
	Danyel Johnson (b) (4)	24 Feb 2021 17:29:31
	(b) (4)	

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered 'un UNK 2011'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:29:31

US3832176

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:29:31



**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2011'	System	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2011'	System	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	24 Feb 2021 17:29:31

**US3832176**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered empty.	System	24 Feb 2021 17:29:31

US3832176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:58:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:50:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:50:59
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Site specific injuries NEC, PT: Limb injury, LLT: Shoulder injury - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:36:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 17:36:00
Data point term sent to Coder	System	24 Feb 2021 17:34:44
User entered 'Right shoulder injury'	Danyel Johnson (b) (4)	24 Feb 2021 17:34:11

**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered 'un UNK 2019'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:34:11

**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:34:11

US3832176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:58:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:34:11



**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered 'un UNK 2019'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:34:11

**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:19
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User entered '0'	(b) (4) Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 17:34:11

US3832176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:58:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2019'	System	24 Feb 2021 17:34:11

**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2019'	System	24 Feb 2021 17:34:11

**US3832176**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'Jan 2019'	System	24 Feb 2021 17:34:11

US3832176

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '2019'	System	24 Feb 2021 17:34:11

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02



**US3832176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered '11:36'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

**US3832176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered '12 Aug 2020 11:36'	System	12 Aug 2020 15:46:02

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered '165.1' cm	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02
DataPoint set to visible.	System	12 Aug 2020 15:29:22

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered '95.5' kg	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02
DataPoint set to visible.	System	12 Aug 2020 15:29:22

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
Amendment Manager: User entered '35.03557'	System	16 Sep 2020 23:53:28
User entered '35.0'	System	12 Aug 2020 15:46:02
DataPoint set to visible.	System	12 Aug 2020 15:29:22

**US3832176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'kg/m2'	System	12 Aug 2020 15:46:02
DataPoint set to visible.	System	12 Aug 2020 15:29:22

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:27
Query 'Per eCRF guidelines, please enter ND.' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	13 Nov 2020 16:23:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:22:34
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:21:23
User entered '97.7' F	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'please delete' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:30
Query 'please delete' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 16:23:43
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	13 Nov 2020 16:22:34
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:21:36
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:46:02



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Folder: Screening

Form: Vital Signs

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[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:33
Query 'Per eCRF guidelines, please enter ND.' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	13 Nov 2020 16:23:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 16:22:34
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:21:45
User entered '81'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

**US3832176**

**Folder: Screening**

**Form: Vital Signs**

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'bpm'	System	12 Aug 2020 15:46:02

US3832176

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:35
Query 'Per eCRF guidelines, please enter ND.' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	13 Nov 2020 16:23:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 16:22:34
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:21:52
User entered '14'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

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[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'breaths/min'	System	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:38
Query 'Per eCRF guidelines, please enter ND.' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	13 Nov 2020 16:23:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	13 Nov 2020 16:22:34
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:22:00
User entered '127'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'mmHg'	System	12 Aug 2020 15:46:02

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:45:49
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 21:45:41
Query 'Per eCRF guidelines, please enter ND.' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	13 Nov 2020 16:23:30
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:22:34
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 13:22:08
User entered '73'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:02



**US3832176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User entered 'mmHg'	System	12 Aug 2020 15:46:02

**US3832176**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12

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Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:31
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:47

US3832176

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:31
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 18:51:11
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		09 Sep 2020 22:13:22
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:30:47

US3832176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02

US3832176

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:58:54

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:46:55
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 12:06:53
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	20 Oct 2020 12:51:09
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 07:13:48
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:02



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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02

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**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02

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Folder: Screening

Form: Childbearing Potential

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Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02

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Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:27
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Un-verified.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:52:53
User entered 'un UNK 1998' reason for change:	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:52:53
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:02

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Folder: Screening

Form: Childbearing Potential

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Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:53:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	09 Feb 2021 16:52:53
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 16:52:53
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:46:55
User entered '1'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:02
	(b) (4)	

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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

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**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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45



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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

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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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:45

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45



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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:37:06
Query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' answered with 'updated' (Site from CRA).	IfDanyel Johnson (b) (4) (b) (4)	12 Nov 2020 18:29:09
User opened query 'please tick subject's living condition below. If none apply, select other and specify (ie Homeless)' ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 13:44:01
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:54

**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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:54

**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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:54

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 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered '0'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

US3832176

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:55:54
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 18:28:36
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:45



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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'please untick. This section is for living conditions only. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:37:09
Query 'please untick. This section is for living conditions only. ' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 18:29:01
User entered '0' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 18:28:36
User opened query 'please untick. This section is for living conditions only. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 13:44:22
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:31:45

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:58:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:12
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:55:54
User closed query 'please delete. This section is for living conditions only. ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:37:11
Query 'please delete. This section is for living conditions only. ' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 18:29:04
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 18:28:36
User opened query 'please delete. This section is for living conditions only. ' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 13:44:37
User entered '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'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:31:45

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:58:48
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:58:48
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:19

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:58:48
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:19

**US3832176**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'VISIT1'	System	12 Aug 2020 15:46:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered '12 AUG 2020'	RWS_ENDPOINT	12 Aug 2020 15:54:20
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:59:06
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:51:43
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:51:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	12 Aug 2020 15:54:20
User entered '185927' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	12 Aug 2020 15:54:20



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Folder: Visit 1 Day 1

Form: Randomization

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered '>=65 years (3)'	RWS_ENDPOINT	12 Aug 2020 15:54:20
	ENDPOINT (b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

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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)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

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)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 15:46:29

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Folder: Visit 1 Day 1

Form: Randomization

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Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:59:06
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 15:46:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:58:54

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
User closed query 'please complete this field.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 15:16:58
	(b) (4), (b) (6)	17 Nov 2020 15:16:54
Query 'please complete this field.' answered with 'Data updated' (Site from CRA).	Danyel Johnson (b) (4)	16 Nov 2020 21:38:01
User entered 'No (N)'	(b) (4)	
	Danyel Johnson (b) (4)	16 Nov 2020 21:37:52
User opened query 'please complete this field.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 21:59:27
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:18:34
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:45:50

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:13
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	(b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:01
User entered '165.1' cm	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:15
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:48
User entered empty; reason for change Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:09
User entered '95.5' kg	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:13
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	(b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:01
User entered '165.1' cm	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:15
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:48
User entered empty; reason for change Data Entry Error	(b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:09
User entered '95.5' kg	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '11:36'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '12 Aug 2020 11:36'	System	12 Aug 2020 17:30:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '97.7' F	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '81'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'bpm'	System	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '14'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'breaths/min'	System	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '127'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23



US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '73'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:13
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:01
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	(b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:11
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:44
User entered empty; reason for change Data Entry Error	(b) (4)	
	(b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:01
User entered '165.1' cm	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User closed query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 22:03:15
Query ' Per eCRF guidelines, please enter ND.' answered with 'Updated' (Site from CRA).	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:10:07
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:09:52
User opened query ' Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
User closed query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:44:21
Query 'Per eCRF guidelines, please enter ND.' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:55:48
User entered empty; reason for change Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	12 Nov 2020 20:55:40
User opened query 'Per eCRF guidelines, please enter ND.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:06:09
User entered '95.5' kg	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

US3832176

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	18 Aug 2020 06:21:09
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).		12 Aug 2020 17:30:23
User entered '12:43'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '12 Aug 2020 12:43'	System	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '98.3' F	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '75'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'bpm'	System	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '14'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'breaths/min'	System	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '110'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:03:22
User entered '73'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	12 Aug 2020 17:30:23

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:04:07
User closed query 'Per eCRF guidelines, please enter No.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:36:18
Query 'Per eCRF guidelines, please enter No.'	Danyel Johnson (b) (4)	12 Nov 2020 20:41:21
answered with 'Updated per query' (Site from CRA).	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 20:41:17
	(b) (4)	
User opened query 'Per eCRF guidelines, please enter No.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:28:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:06:47
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:04:07
User closed query 'please delete date' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 00:36:24
Query 'please delete date' answered with 'Updated per query' (Site from CRA).	Danyel Johnson (b) (4)	12 Nov 2020 20:41:25
User entered empty; reason for change Data Entry Error	(b) (4) Danyel Johnson (b) (4)	12 Nov 2020 20:41:17
User opened query 'please delete date' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:28:04
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:06:47

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered empty.	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'MRNA-1273 OR PLACEBO'	System	12 Aug 2020 16:16:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered '12:13'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '12 Aug 2020 12:13'	System	12 Aug 2020 16:16:56

US3832176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:16:56

US3832176

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:15
User entered 'ONCE'	System	12 Aug 2020 16:16:56



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'INTRAMUSCULAR'	System	12 Aug 2020 16:16:56

US3832176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:35
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:06:58

US3832176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:35
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:06:58

US3832176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:35
User entered '12:02'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:06:58

US3832176

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '12 Aug 2020 12:02'	System	12 Aug 2020 16:06:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:48
User entered '12 Aug 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:04:48
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:07:13



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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:04:48
User entered '12:00'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:04:48
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 17:38:41
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:04:48
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 17:38:41
User entered '12:00'	(b) (4) Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered empty.	System	11 Nov 2020 17:38:41
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 16:07:13

US3832176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:03
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:07:29

US3832176

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	12 Aug 2020 16:07:29



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:42:43', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8e70d7e4-76b0-4fa3-887e-2029db8f48d8' User entered 'Yes (Y)'	System	12 Aug 2020 16:43:08
	System	12 Aug 2020 16:43:08

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:42:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8e70d7e4-76b0-4fa3-887e-2029db8f48d8' User entered '98.3'	System	12 Aug 2020 16:43:08
	System	12 Aug 2020 16:43:08

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8e70d7e4-76b0-4fa3-887e-2029db8f48d8'	System	12 Aug 2020 16:43:08
User entered 'No (N)'	System	12 Aug 2020 16:43:08

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:06', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8e70d7e4-76b0-4fa3-887e-2029db8f48d8'	System	12 Aug 2020 16:43:08
User entered '12 Aug 2020 12:43'	System	12 Aug 2020 16:43:08

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 12:33'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:03'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:19:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40e0947e-1456-486e-ad8f-eb3778c8d13b' User entered 'Yes (Y)'	System	12 Aug 2020 20:19:51
	System	12 Aug 2020 20:19:51

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:19:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40e0947e-1456-486e-ad8f-eb3778c8d13b' User entered '98.2'	System	12 Aug 2020 20:19:51
	System	12 Aug 2020 20:19:51

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:19:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40e0947e-1456-486e-ad8f-eb3778c8d13b'	System	12 Aug 2020 20:19:51
User entered 'No (N)'	System	12 Aug 2020 20:19:51

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:19:47', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40e0947e-1456-486e-ad8f-eb3778c8d13b' User entered '12 Aug 2020 16:19'	System	12 Aug 2020 20:19:51
	System	12 Aug 2020 20:19:51

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:58'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 2'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:40:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd0b23c7e-b143-4db3-8662-f8e18b785d64' User entered 'Yes (Y)'	System	14 Aug 2020 01:40:49
	System	14 Aug 2020 01:40:49



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:40:34', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd0b23c7e-b143-4db3-8662-f8e18b785d64' User entered '98.2'	System	14 Aug 2020 01:40:49
	System	14 Aug 2020 01:40:49

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:40:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd0b23c7e-b143-4db3-8662-f8e18b785d64'	System	14 Aug 2020 01:40:49
User entered 'No (N)'	System	14 Aug 2020 01:40:49

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:40:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd0b23c7e-b143-4db3-8662-f8e18b785d64'	System	14 Aug 2020 01:40:49
User entered '13 Aug 2020 21:40'	System	14 Aug 2020 01:40:49

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 3'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:07', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06fa8bfc-1f99-4efd-8193-192faa0626d6'	System	14 Aug 2020 18:48:47
User entered 'Yes (Y)'	System	14 Aug 2020 18:48:47

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06fa8bfc-1f99-4efd-8193-192faa0626d6' User entered '97.8'	System	14 Aug 2020 18:48:47
	System	14 Aug 2020 18:48:47



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06fa8bfc-1f99-4efd-8193-192faa0626d6'	System	14 Aug 2020 18:48:47
User entered 'No (N)'	System	14 Aug 2020 18:48:47

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06fa8bfc-1f99-4efd-8193-192faa0626d6'	System	14 Aug 2020 18:48:47
User entered '14 Aug 2020 14:48'	System	14 Aug 2020 18:48:47

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 4'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:14:27', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '78aebc58-bd95-4220-b892-91657e64a6d1'	System	15 Aug 2020 23:14:53
User entered 'Yes (Y)'	System	15 Aug 2020 23:14:53

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:14:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '78aebc58-bd95-4220-b892-91657e64a6d1' User entered '97.8'	System	15 Aug 2020 23:14:53
	System	15 Aug 2020 23:14:53

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:14:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '78aebc58-bd95-4220-b892-91657e64a6d1'	System	15 Aug 2020 23:14:53
User entered 'No (N)'	System	15 Aug 2020 23:14:53



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:14:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '78aebc58-bd95-4220-b892-91657e64a6d1'	System	15 Aug 2020 23:14:53
User entered '15 Aug 2020 19:14'	System	15 Aug 2020 23:14:53

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 5'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:54:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a5429aa0-f616-4de8-8316-d3436dfcc492' User entered 'Yes (Y)'	System	17 Aug 2020 00:55:05
	System	17 Aug 2020 00:55:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:54:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a5429aa0-f616-4de8-8316-d3436dfcc492' User entered '98.0'	System	17 Aug 2020 00:55:05
	System	17 Aug 2020 00:55:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:54:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a5429aa0-f616-4de8-8316-d3436dfcc492'	System	17 Aug 2020 00:55:05
User entered 'No (N)'	System	17 Aug 2020 00:55:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a5429aa0-f616-4de8-8316-d3436dfcc492'	System	17 Aug 2020 00:55:05
User entered '16 Aug 2020 20:55'	System	17 Aug 2020 00:55:05



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 6'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:16', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3609e222-4753-481a-ada7-e03d3e07f2e6' User entered 'No (N)'	System	18 Aug 2020 11:57:29
	System	18 Aug 2020 11:57:29

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:20', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3609e222-4753-481a-ada7-e03d3e07f2e6'	System	18 Aug 2020 11:57:29
User entered 'No (N)'	System	18 Aug 2020 11:57:29

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3609e222-4753-481a-ada7-e03d3e07f2e6' User entered '18 Aug 2020 07:57'	System	18 Aug 2020 11:57:29
	System	18 Aug 2020 11:57:29

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 7'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:23:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '135743fe-8009-4f7f-848d-4a1d65e332f1' User entered 'Yes (Y)'	System	19 Aug 2020 15:24:05
	System	19 Aug 2020 15:24:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:23:54', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '135743fe-8009-4f7f-848d-4a1d65e332f1' User entered '97.5'	System	19 Aug 2020 15:24:05
	System	19 Aug 2020 15:24:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:23:57', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '135743fe-8009-4f7f-848d-4a1d65e332f1'	System	19 Aug 2020 15:24:05
User entered 'No (N)'	System	19 Aug 2020 15:24:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '135743fe-8009-4f7f-848d-4a1d65e332f1' User entered '19 Aug 2020 11:24'	System	19 Aug 2020 15:24:05
	System	19 Aug 2020 15:24:05

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e34a224e-cef6-47c0-9151-e7c5323ddb9'	System	12 Aug 2020 16:43:55
User entered 'None (1)'	System	12 Aug 2020 16:43:55

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e34a224e-cef6-47c0-9151-e7c5323ddb9'	System	12 Aug 2020 16:43:55
User entered 'No (N)'	System	12 Aug 2020 16:43:55

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e34a224e-cef6-47c0-9151-e7c5323ddb9'	System	12 Aug 2020 16:43:55
User entered 'No (N)'	System	12 Aug 2020 16:43:55

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e34a224e-cef6-47c0-9151-e7c5323ddb9'	System	12 Aug 2020 16:43:55
User entered 'None (1)'	System	12 Aug 2020 16:43:55

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e34a224e-cef6-47c0-9151-e7c5323ddb9'	System	12 Aug 2020 16:43:55
User entered '12 Aug 2020 12:43'	System	12 Aug 2020 16:43:55

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 12:33'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:03'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4590a965-a599-4751-9a23-9a58067e546b' User entered 'None (1)'	System	12 Aug 2020 20:20:34
	System	12 Aug 2020 20:20:34

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:05', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4590a965-a599-4751-9a23-9a58067e546b' User entered 'No (N)'	System	12 Aug 2020 20:20:34
	System	12 Aug 2020 20:20:34

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4590a965-a599-4751-9a23-9a58067e546b' User entered 'No (N)'	System	12 Aug 2020 20:20:34
	System	12 Aug 2020 20:20:34

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:24', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4590a965-a599-4751-9a23-9a58067e546b' User entered 'None (1)'	System	12 Aug 2020 20:20:34
	System	12 Aug 2020 20:20:34

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4590a965-a599-4751-9a23-9a58067e546b' User entered '12 Aug 2020 16:20'	System	12 Aug 2020 20:20:34
	System	12 Aug 2020 20:20:34

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:58'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 2'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:40:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40b3cea1-1ca4-4483-8f43-5428c05a1127'	System	14 Aug 2020 01:41:18
User entered 'None (1)'	System	14 Aug 2020 01:41:18

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40b3cea1-1ca4-4483-8f43-5428c05a1127'	System	14 Aug 2020 01:41:18
User entered 'No (N)'	System	14 Aug 2020 01:41:18

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:06', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40b3cea1-1ca4-4483-8f43-5428c05a1127'	System	14 Aug 2020 01:41:18
User entered 'No (N)'	System	14 Aug 2020 01:41:18

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:11', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40b3cea1-1ca4-4483-8f43-5428c05a1127'	System	14 Aug 2020 01:41:18
User entered 'None (1)'	System	14 Aug 2020 01:41:18

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:16', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40b3cea1-1ca4-4483-8f43-5428c05a1127'	System	14 Aug 2020 01:41:18
User entered '13 Aug 2020 21:41'	System	14 Aug 2020 01:41:18

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 3'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40977c33-1c67-4729-bedf-68fbb684ca6b' User entered 'None (1)'	System	14 Aug 2020 18:49:09
	System	14 Aug 2020 18:49:09

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:53', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40977c33-1c67-4729-bedf-68fbb684ca6b' User entered 'No (N)'	System	14 Aug 2020 18:49:09
	System	14 Aug 2020 18:49:09

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40977c33-1c67-4729-bedf-68fbb684ca6b' User entered 'No (N)'	System	14 Aug 2020 18:49:09
	System	14 Aug 2020 18:49:09

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:48:59', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40977c33-1c67-4729-bedf-68fbb684ca6b' User entered 'None (1)'	System	14 Aug 2020 18:49:09
	System	14 Aug 2020 18:49:09

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:07', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '40977c33-1c67-4729-bedf-68fbb684ca6b' User entered '14 Aug 2020 14:49'	System	14 Aug 2020 18:49:09
	System	14 Aug 2020 18:49:09

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 4'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '88dda7a7-7b8a-47c5-8c52-dc113c92c334'	System	15 Aug 2020 23:15:21
User entered 'None (1)'	System	15 Aug 2020 23:15:21

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '88dda7a7-7b8a-47c5-8c52-dc113c92c334'	System	15 Aug 2020 23:15:21
User entered 'No (N)'	System	15 Aug 2020 23:15:21

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '88dda7a7-7b8a-47c5-8c52-dc113c92c334'	System	15 Aug 2020 23:15:21
User entered 'No (N)'	System	15 Aug 2020 23:15:21

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '88dda7a7-7b8a-47c5-8c52-dc113c92c334'	System	15 Aug 2020 23:15:21
User entered 'None (1)'	System	15 Aug 2020 23:15:21

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '88dda7a7-7b8a-47c5-8c52-dc113c92c334'	System	15 Aug 2020 23:15:21
User entered '15 Aug 2020 19:15'	System	15 Aug 2020 23:15:21

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 5'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '29e9b42a-928d-4efb-b430-61bee96215da' User entered 'None (1)'	System	17 Aug 2020 00:55:31
	System	17 Aug 2020 00:55:31

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '29e9b42a-928d-4efb-b430-61bee96215da' User entered 'No (N)'	System	17 Aug 2020 00:55:31
	System	17 Aug 2020 00:55:31

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '29e9b42a-928d-4efb-b430-61bee96215da' User entered 'No (N)'	System	17 Aug 2020 00:55:31
	System	17 Aug 2020 00:55:31

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '29e9b42a-928d-4efb-b430-61bee96215da' User entered 'None (1)'	System	17 Aug 2020 00:55:31
	System	17 Aug 2020 00:55:31

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:55:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '29e9b42a-928d-4efb-b430-61bee96215da' User entered '16 Aug 2020 20:55'	System	17 Aug 2020 00:55:31
	System	17 Aug 2020 00:55:31

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 6'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4c74b6c4-8329-462d-abad-39ed08923511' User entered 'None (1)'	System	18 Aug 2020 11:57:49
	System	18 Aug 2020 11:57:49

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:35', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4c74b6c4-8329-462d-abad-39ed08923511'	System	18 Aug 2020 11:57:49
User entered 'No (N)'	System	18 Aug 2020 11:57:49

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4c74b6c4-8329-462d-abad-39ed08923511' User entered 'No (N)'	System	18 Aug 2020 11:57:49
	System	18 Aug 2020 11:57:49

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4c74b6c4-8329-462d-abad-39ed08923511' User entered 'None (1)'	System	18 Aug 2020 11:57:49
	System	18 Aug 2020 11:57:49

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:47', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4c74b6c4-8329-462d-abad-39ed08923511' User entered '18 Aug 2020 07:57'	System	18 Aug 2020 11:57:49
	System	18 Aug 2020 11:57:49

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 7'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:08', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7aba6448-95b2-4884-a4c1-e74a11cae66d' User entered 'None (1)'	System	19 Aug 2020 15:24:28
	System	19 Aug 2020 15:24:28

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:11', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7aba6448-95b2-4884-a4c1-e74a11cae66d' User entered 'No (N)'	System	19 Aug 2020 15:24:28
	System	19 Aug 2020 15:24:28

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7aba6448-95b2-4884-a4c1-e74a11cae66d' User entered 'No (N)'	System	19 Aug 2020 15:24:28
	System	19 Aug 2020 15:24:28

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7aba6448-95b2-4884-a4c1-e74a11cae66d'	System	19 Aug 2020 15:24:28
User entered 'None (1)'	System	19 Aug 2020 15:24:28

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7aba6448-95b2-4884-a4c1-e74a11cae66d' User entered '19 Aug 2020 11:24'	System	19 Aug 2020 15:24:28
	System	19 Aug 2020 15:24:28

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:52', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:43:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:44:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:44:03', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:44:05', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'None (0)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:44:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered 'No (N)'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T12:44:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'c4c00901-808a-4ea2-a054-0a0e73f1a07d' User entered '12 Aug 2020 12:44'	System	12 Aug 2020 16:44:22
	System	12 Aug 2020 16:44:22



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 12:33'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:03'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 1, after vaccination (at home)'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:40', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:54', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:20:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:21:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4' User entered 'None (0)'	System	12 Aug 2020 20:21:17
	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:21:08', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4'	System	12 Aug 2020 20:21:17
User entered 'No (N)'	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-12T16:21:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ba140367-08fb-4337-9780-ac63a0ab4bf4'	System	12 Aug 2020 20:21:17
User entered '12 Aug 2020 16:21'	System	12 Aug 2020 20:21:17

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Aug 2020 15:58'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 2'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:34', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:40', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'None (0)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:43', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered 'No (N)'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-13T21:41:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '735be554-246c-4db5-97a4-684fd35dace1' User entered '13 Aug 2020 21:41'	System	14 Aug 2020 01:41:52
	System	14 Aug 2020 01:41:52

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 11:59'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 3'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:15', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:18', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:21', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:27', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'None (0)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered 'No (N)'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-14T14:49:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd788052c-100d-47b8-adfe-b7842640e183' User entered '14 Aug 2020 14:49'	System	14 Aug 2020 18:49:43
	System	14 Aug 2020 18:49:43

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 4'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:34', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'None (0)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:47', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered 'No (N)'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-15T19:15:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '19325cf4-08e6-4e0b-8b31-b7609e8a2c8b' User entered '15 Aug 2020 19:15'	System	15 Aug 2020 23:16:00
	System	15 Aug 2020 23:16:00

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 5'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469'	System	17 Aug 2020 00:57:05
User entered 'No interference with activity (1)'	System	17 Aug 2020 00:57:05



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:07', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469' User entered 'None (0)'	System	17 Aug 2020 00:57:05
	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:12', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469' User entered 'None (0)'	System	17 Aug 2020 00:57:05
	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:27', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469'	System	17 Aug 2020 00:57:05
User entered 'No interference with activity (1)'	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469'	System	17 Aug 2020 00:57:05
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469' User entered 'None (0)'	System	17 Aug 2020 00:57:05
	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:56:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469'	System	17 Aug 2020 00:57:05
User entered 'No (N)'	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-16T20:57:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fb13e7f7-1e28-47c7-ab24-e49b653b0469'	System	17 Aug 2020 00:57:05
User entered '16 Aug 2020 20:57'	System	17 Aug 2020 00:57:05

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Aug 2020 12:00'	System	12 Aug 2020 16:16:56



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 6'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:52', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:57:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:58:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:58:05', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:58:08', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'None (0)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:58:13', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered 'No (N)'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-18T07:58:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8a341ac6-3b8e-4e76-bc32-a8ce1425b826' User entered '18 Aug 2020 07:58'	System	18 Aug 2020 11:58:19
	System	18 Aug 2020 11:58:19

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '17 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 7'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered 'None (0)'	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered 'None (0)'	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:36', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered 'None (0)'	System	19 Aug 2020 15:25:04



US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503' User entered 'None (0)'	System	19 Aug 2020 15:25:04
	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503' User entered 'None (0)'	System	19 Aug 2020 15:25:04
	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered 'None (0)'	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered 'No (N)'	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-08-19T11:24:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '8c2fe274-e6e5-4fac-9691-dfce4b1f6503'	System	19 Aug 2020 15:25:04
User entered '19 Aug 2020 11:24'	System	19 Aug 2020 15:25:04

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '18 Aug 2020 12:00'	System	12 Aug 2020 16:16:56

US3832176

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '19 Aug 2020 11:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:31
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 20:24:54



US3832176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:31
User entered '19 Aug 2020'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 20:24:54

US3832176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:31
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 20:24:54

US3832176

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:05:31
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 20:24:54

US3832176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:37
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 20:24:59

US3832176

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	19 Aug 2020 20:24:59

US3832176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:46
User entered 'Yes (Y)'	Emma Partin (b) (4)	26 Aug 2020 13:22:53

US3832176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:46
User entered '26 Aug 2020'	Emma Partin (b) (4)	26 Aug 2020 13:22:53

US3832176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:05:46
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	26 Aug 2020 13:22:53



US3832176

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:05:46
User entered empty.	Emma Partin (b) (4) (b) (4)	26 Aug 2020 13:22:53

US3832176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:05:55
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	26 Aug 2020 13:22:58

US3832176

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	26 Aug 2020 13:22:58

US3832176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:20:41

US3832176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:02
User entered '2 Sep 2020'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:20:41

US3832176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:02
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:20:41

US3832176

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:02
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:20:41

US3832176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:07
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:20:50



US3832176

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	02 Sep 2020 12:20:50

US3832176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:45:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:13:22

US3832176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:45:45
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:13:22

US3832176

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:45:45
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	09 Sep 2020 22:13:22

**US3832176**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'VISIT2'	System	09 Sep 2020 22:13:22

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:14:30



US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '11:18'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '09 Sep 2020 11:18'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '97.2' F	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered 'Oral (Oral)'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered empty.	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '68'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'bpm'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '17'	Emma Partin (b) (4)	09 Sep 2020 22:14:30



US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'breaths/min'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '125'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '85'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:14:30



US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '12:16'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '09 Sep 2020 12:16'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '97.2' F	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered 'Oral (Oral)'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered empty.	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '72'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'bpm'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '16'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:14:30



US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'breaths/min'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '128'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:13
User entered '80'	Emma Partin (b) (4)	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	09 Sep 2020 22:14:30

US3832176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:45:54
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:14:43

US3832176

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:45:54
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:14:43

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 15:44:33



US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered '9 Sep 2020'	(b) (4), (b) (6)	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered '11:40'	(b) (4), (b) (6)	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '9 Sep 2020 11:40'	System	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:59
User entered 'ONCE'	System	09 Sep 2020 15:44:33



US3832176

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 15:44:33

US3832176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:50
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:15:03

US3832176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:50
User entered '9 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:15:03

US3832176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:50
User entered '11:31'	Emma Partin (b) (4)	09 Sep 2020 22:15:03

US3832176

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '9 Sep 2020 11:31'	System	09 Sep 2020 22:15:03

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:58:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:33
User entered '09 Sep 2020'	Emma Partin (b) (4)	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:33
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:15:21



US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:46:33
User entered '11:26'	Emma Partin (b) (4)	09 Sep 2020 22:15:21

**US3832176**

**Folder: Visit 2 Day 29 (1)**

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

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '09 Sep 2020 11:26'	System	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:46:33
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 17:38:24
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:46:33
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 17:38:24
User entered '11:26'	(b) (4) Emma Partin (b) (4) (b) (4)	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered empty.	System	11 Nov 2020 17:38:24
User entered '09 Sep 2020 11:26'	System	09 Sep 2020 22:15:21

US3832176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:08
User entered 'Yes (Y)'	Emma Partin (b) (4)	09 Sep 2020 22:15:25

US3832176

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	09 Sep 2020 22:15:25



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:18:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '342c0e6f-e8f6-449c-97b8-7b81fc437214' User entered 'Yes (Y)'	System	09 Sep 2020 16:19:10
	System	09 Sep 2020 16:19:10

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:18:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '342c0e6f-e8f6-449c-97b8-7b81fc437214' User entered '97.2'	System	09 Sep 2020 16:19:10
	System	09 Sep 2020 16:19:10

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:18:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '342c0e6f-e8f6-449c-97b8-7b81fc437214'	System	09 Sep 2020 16:19:10
User entered 'No (N)'	System	09 Sep 2020 16:19:10

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '342c0e6f-e8f6-449c-97b8-7b81fc437214' User entered '09 Sep 2020 12:19'	System	09 Sep 2020 16:19:10
	System	09 Sep 2020 16:19:10

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 14:30'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:10', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4db7ebb2-4a56-4fdc-82b5-f3796ebae01d' User entered 'Yes (Y)'	System	10 Sep 2020 00:42:35
	System	10 Sep 2020 00:42:35

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:21', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4db7ebb2-4a56-4fdc-82b5-f3796ebae01d' User entered '97.8'	System	10 Sep 2020 00:42:35
	System	10 Sep 2020 00:42:35

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:25', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4db7ebb2-4a56-4fdc-82b5-f3796ebae01d' User entered 'No (N)'	System	10 Sep 2020 00:42:35
	System	10 Sep 2020 00:42:35

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4db7ebb2-4a56-4fdc-82b5-f3796ebae01d' User entered '09 Sep 2020 20:42'	System	10 Sep 2020 00:42:35
	System	10 Sep 2020 00:42:35

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 15:25'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 2'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:07:53', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd85361e0-6cce-4a98-859a-b0b1bb2bafc1' User entered 'Yes (Y)'	System	11 Sep 2020 01:08:18
	System	11 Sep 2020 01:08:18



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd85361e0-6cce-4a98-859a-b0b1bb2bafc1' User entered '98.2'	System	11 Sep 2020 01:08:18
	System	11 Sep 2020 01:08:18

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd85361e0-6cce-4a98-859a-b0b1bb2bafc1' User entered 'No (N)'	System	11 Sep 2020 01:08:18
	System	11 Sep 2020 01:08:18

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'd85361e0-6cce-4a98-859a-b0b1bb2bafc1' User entered '10 Sep 2020 21:08'	System	11 Sep 2020 01:08:18
	System	11 Sep 2020 01:08:18

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 3'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:23:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '57143283-2030-4d25-b61e-794552f0c89e' User entered 'Yes (Y)'	System	11 Sep 2020 21:23:52
	System	11 Sep 2020 21:23:52

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:23:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '57143283-2030-4d25-b61e-794552f0c89e' User entered '97.8'	System	11 Sep 2020 21:23:52
	System	11 Sep 2020 21:23:52



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:23:43', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '57143283-2030-4d25-b61e-794552f0c89e' User entered 'No (N)'	System	11 Sep 2020 21:23:52
	System	11 Sep 2020 21:23:52

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:23:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '57143283-2030-4d25-b61e-794552f0c89e' User entered '11 Sep 2020 17:23'	System	11 Sep 2020 21:23:52
	System	11 Sep 2020 21:23:52

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 4'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:52:52', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4402fe9f-df59-42dd-9e07-f39ec8f313d3'	System	12 Sep 2020 23:53:14
User entered 'Yes (Y)'	System	12 Sep 2020 23:53:14

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:52:59', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4402fe9f-df59-42dd-9e07-f39ec8f313d3' User entered '97.8'	System	12 Sep 2020 23:53:14
	System	12 Sep 2020 23:53:14

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4402fe9f-df59-42dd-9e07-f39ec8f313d3'	System	12 Sep 2020 23:53:14
User entered 'No (N)'	System	12 Sep 2020 23:53:14



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4402fe9f-df59-42dd-9e07-f39ec8f313d3'	System	12 Sep 2020 23:53:14
User entered '12 Sep 2020 19:53'	System	12 Sep 2020 23:53:14

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 5'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '45d30d5f-4351-415a-906d-7cf50de26ae0' User entered 'Yes (Y)'	System	14 Sep 2020 03:09:27
	System	14 Sep 2020 03:09:27

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:08', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '45d30d5f-4351-415a-906d-7cf50de26ae0' User entered '98.2'	System	14 Sep 2020 03:09:27
	System	14 Sep 2020 03:09:27

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:15', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '45d30d5f-4351-415a-906d-7cf50de26ae0' User entered 'No (N)'	System	14 Sep 2020 03:09:27
	System	14 Sep 2020 03:09:27

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '45d30d5f-4351-415a-906d-7cf50de26ae0' User entered '13 Sep 2020 23:09'	System	14 Sep 2020 03:09:27
	System	14 Sep 2020 03:09:27



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 6'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:44:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0b9641c6-1842-4f70-bea8-6066549c0c01' User entered 'Yes (Y)'	System	15 Sep 2020 05:45:06
	System	15 Sep 2020 05:45:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:44:54', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0b9641c6-1842-4f70-bea8-6066549c0c01' User entered '97.8'	System	15 Sep 2020 05:45:06
	System	15 Sep 2020 05:45:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:44:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0b9641c6-1842-4f70-bea8-6066549c0c01' User entered 'No (N)'	System	15 Sep 2020 05:45:06
	System	15 Sep 2020 05:45:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0b9641c6-1842-4f70-bea8-6066549c0c01' User entered '15 Sep 2020 01:45'	System	15 Sep 2020 05:45:06
	System	15 Sep 2020 05:45:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 7'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:05:45', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4d9507fd-0df3-46a4-8fd2-3e472b9826e6' User entered 'Yes (Y)'	System	16 Sep 2020 13:06:06
	System	16 Sep 2020 13:06:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:05:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4d9507fd-0df3-46a4-8fd2-3e472b9826e6' User entered '97.8'	System	16 Sep 2020 13:06:06
	System	16 Sep 2020 13:06:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:05:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4d9507fd-0df3-46a4-8fd2-3e472b9826e6'	System	16 Sep 2020 13:06:06
User entered 'No (N)'	System	16 Sep 2020 13:06:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4d9507fd-0df3-46a4-8fd2-3e472b9826e6' User entered '16 Sep 2020 09:06'	System	16 Sep 2020 13:06:06
	System	16 Sep 2020 13:06:06

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '53e647f8-8acc-4528-885a-ab1eb91de21f' User entered 'None (1)'	System	09 Sep 2020 16:19:42
	System	09 Sep 2020 16:19:42

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '53e647f8-8acc-4528-885a-ab1eb91de21f' User entered 'No (N)'	System	09 Sep 2020 16:19:42
	System	09 Sep 2020 16:19:42

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '53e647f8-8acc-4528-885a-ab1eb91de21f' User entered 'No (N)'	System	09 Sep 2020 16:19:42
	System	09 Sep 2020 16:19:42

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '53e647f8-8acc-4528-885a-ab1eb91de21f' User entered 'None (1)'	System	09 Sep 2020 16:19:42
	System	09 Sep 2020 16:19:42

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '53e647f8-8acc-4528-885a-ab1eb91de21f' User entered '09 Sep 2020 12:19'	System	09 Sep 2020 16:19:42
	System	09 Sep 2020 16:19:42

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 14:30'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b995fc0d-b627-4416-ad96-dc2513913592'	System	10 Sep 2020 00:43:10
User entered 'None (1)'	System	10 Sep 2020 00:43:10

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:40', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b995fc0d-b627-4416-ad96-dc2513913592'	System	10 Sep 2020 00:43:10
User entered 'No (N)'	System	10 Sep 2020 00:43:10

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b995fc0d-b627-4416-ad96-dc2513913592'	System	10 Sep 2020 00:43:10
User entered 'No (N)'	System	10 Sep 2020 00:43:10

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:42:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b995fc0d-b627-4416-ad96-dc2513913592'	System	10 Sep 2020 00:43:10
User entered 'None (1)'	System	10 Sep 2020 00:43:10

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:07', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b995fc0d-b627-4416-ad96-dc2513913592' User entered '09 Sep 2020 20:43'	System	10 Sep 2020 00:43:10
	System	10 Sep 2020 00:43:10

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 15:25'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 2'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5865c13f-68c2-4195-adb2-c3e181ddff35'	System	11 Sep 2020 01:08:50
User entered 'None (1)'	System	11 Sep 2020 01:08:50

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5865c13f-68c2-4195-adb2-c3e181ddff35'	System	11 Sep 2020 01:08:50
User entered 'No (N)'	System	11 Sep 2020 01:08:50

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:34', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5865c13f-68c2-4195-adb2-c3e181ddff35'	System	11 Sep 2020 01:08:50
User entered 'No (N)'	System	11 Sep 2020 01:08:50

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5865c13f-68c2-4195-adb2-c3e181ddff35'	System	11 Sep 2020 01:08:50
User entered 'None (1)'	System	11 Sep 2020 01:08:50

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5865c13f-68c2-4195-adb2-c3e181ddff35' User entered '10 Sep 2020 21:08'	System	11 Sep 2020 01:08:50
	System	11 Sep 2020 01:08:50

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 3'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:23:57', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '016cad15-8ff0-45ad-a347-e4d93d3f027f' User entered 'None (1)'	System	11 Sep 2020 21:24:22
	System	11 Sep 2020 21:24:22

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '016cad15-8ff0-45ad-a347-e4d93d3f027f' User entered 'No (N)'	System	11 Sep 2020 21:24:22
	System	11 Sep 2020 21:24:22

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:05', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '016cad15-8ff0-45ad-a347-e4d93d3f027f' User entered 'No (N)'	System	11 Sep 2020 21:24:22
	System	11 Sep 2020 21:24:22

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:10', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '016cad15-8ff0-45ad-a347-e4d93d3f027f' User entered 'None (1)'	System	11 Sep 2020 21:24:22
	System	11 Sep 2020 21:24:22

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '016cad15-8ff0-45ad-a347-e4d93d3f027f' User entered '11 Sep 2020 17:24'	System	11 Sep 2020 21:24:22
	System	11 Sep 2020 21:24:22

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 4'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '01a22308-30fb-4988-bf13-f5bb39d661d0'	System	12 Sep 2020 23:53:38
User entered 'None (1)'	System	12 Sep 2020 23:53:38

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:18', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '01a22308-30fb-4988-bf13-f5bb39d661d0' User entered 'No (N)'	System	12 Sep 2020 23:53:38
	System	12 Sep 2020 23:53:38

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:24', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '01a22308-30fb-4988-bf13-f5bb39d661d0' User entered 'No (N)'	System	12 Sep 2020 23:53:38
	System	12 Sep 2020 23:53:38

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:27', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '01a22308-30fb-4988-bf13-f5bb39d661d0'	System	12 Sep 2020 23:53:38
User entered 'None (1)'	System	12 Sep 2020 23:53:38

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:32', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '01a22308-30fb-4988-bf13-f5bb39d661d0' User entered '12 Sep 2020 19:53'	System	12 Sep 2020 23:53:38
	System	12 Sep 2020 23:53:38

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 5'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e27bf347-9021-4e68-97a0-04b75c9ac117' User entered 'None (1)'	System	14 Sep 2020 03:09:55
	System	14 Sep 2020 03:09:55

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:35', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e27bf347-9021-4e68-97a0-04b75c9ac117' User entered 'No (N)'	System	14 Sep 2020 03:09:55
	System	14 Sep 2020 03:09:55

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e27bf347-9021-4e68-97a0-04b75c9ac117' User entered 'No (N)'	System	14 Sep 2020 03:09:55
	System	14 Sep 2020 03:09:55

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e27bf347-9021-4e68-97a0-04b75c9ac117' User entered 'None (1)'	System	14 Sep 2020 03:09:55
	System	14 Sep 2020 03:09:55

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e27bf347-9021-4e68-97a0-04b75c9ac117'	System	14 Sep 2020 03:09:55
User entered '13 Sep 2020 23:09'	System	14 Sep 2020 03:09:55

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 6'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '24587055-1550-4b16-a46e-2ce1bb34aa01'	System	15 Sep 2020 05:45:30
User entered 'None (1)'	System	15 Sep 2020 05:45:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '24587055-1550-4b16-a46e-2ce1bb34aa01'	System	15 Sep 2020 05:45:30
User entered 'No (N)'	System	15 Sep 2020 05:45:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:18', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '24587055-1550-4b16-a46e-2ce1bb34aa01' User entered 'No (N)'	System	15 Sep 2020 05:45:30
	System	15 Sep 2020 05:45:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:21', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '24587055-1550-4b16-a46e-2ce1bb34aa01'	System	15 Sep 2020 05:45:30
User entered 'None (1)'	System	15 Sep 2020 05:45:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '24587055-1550-4b16-a46e-2ce1bb34aa01' User entered '15 Sep 2020 01:45'	System	15 Sep 2020 05:45:30
	System	15 Sep 2020 05:45:30

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 7'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:06', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0f6327f0-c6d9-4a58-8008-30b6b35d54df' User entered 'None (1)'	System	16 Sep 2020 13:06:23
	System	16 Sep 2020 13:06:23

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0f6327f0-c6d9-4a58-8008-30b6b35d54df' User entered 'No (N)'	System	16 Sep 2020 13:06:23
	System	16 Sep 2020 13:06:23

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:12', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0f6327f0-c6d9-4a58-8008-30b6b35d54df' User entered 'No (N)'	System	16 Sep 2020 13:06:23
	System	16 Sep 2020 13:06:23

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:15', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0f6327f0-c6d9-4a58-8008-30b6b35d54df' User entered 'None (1)'	System	16 Sep 2020 13:06:23
	System	16 Sep 2020 13:06:23

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:21', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0f6327f0-c6d9-4a58-8008-30b6b35d54df' User entered '16 Sep 2020 09:06'	System	16 Sep 2020 13:06:23
	System	16 Sep 2020 13:06:23

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:49', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:53', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'None (0)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:19:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered 'No (N)'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T12:20:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '30ad4069-1ffa-4203-aca0-9e6ce5eed4a7' User entered '09 Sep 2020 12:20'	System	09 Sep 2020 16:20:05
	System	09 Sep 2020 16:20:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 14:30'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:16', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:22', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:32', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered 'None (0)'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65'	System	10 Sep 2020 00:43:49
User entered 'No (N)'	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-09T20:43:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51b9cf02-5dd5-422a-bdfb-c25a8f661e65' User entered '09 Sep 2020 20:43'	System	10 Sep 2020 00:43:49
	System	10 Sep 2020 00:43:49

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '09 Sep 2020 15:25'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 2'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:54', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:08:57', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:07', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'None (0)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:16', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered 'No (N)'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-10T21:09:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '838fd946-af96-43c4-b4b6-8a8b20a747e4' User entered '10 Sep 2020 21:09'	System	11 Sep 2020 01:09:25
	System	11 Sep 2020 01:09:25

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 3'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:36', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'None (0)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:24:47', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470' User entered 'No (N)'	System	11 Sep 2020 21:25:22
	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-11T17:25:20', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e8a8eecf-56ac-4744-adaa-e88524bb7470'	System	11 Sep 2020 21:25:22
User entered '11 Sep 2020 17:25'	System	11 Sep 2020 21:25:22

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 4'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:44', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:46', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:49', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:52', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'None (0)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:53:56', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered 'No (N)'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

**US3832176**

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

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

**Generated On: 10 Jun 2021 09:58:54**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-12T19:54:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a3d428da-1b13-45b4-8365-d1219d00bdc8' User entered '12 Sep 2020 19:54'	System	12 Sep 2020 23:54:07
	System	12 Sep 2020 23:54:07

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 5'	System	09 Sep 2020 15:44:33



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:09:58', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:03', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:06', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:09', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:12', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'None (0)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:17', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474' User entered 'No (N)'	System	14 Sep 2020 03:10:28
	System	14 Sep 2020 03:10:28

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-13T23:10:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fc113d56-d0d0-4b33-b2fa-fe57e0502474'	System	14 Sep 2020 03:10:28
User entered '13 Sep 2020 23:10'	System	14 Sep 2020 03:10:28



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 6'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:34', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:40', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:43', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:47', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'None (0)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:45:55', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered 'No (N)'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-15T01:46:03', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b9f7133d-ccec-4fb6-b23f-937944ced14b' User entered '15 Sep 2020 01:46'	System	15 Sep 2020 05:46:05
	System	15 Sep 2020 05:46:05

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

**US3832176**

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

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

**Generated On: 10 Jun 2021 09:58:54**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	09 Sep 2020 15:44:33
User entered 'Day 7'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50



US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:36', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'None (0)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:42', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered 'No (N)'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-09-16T09:06:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3a440a47-23e7-4572-9109-f02c1919af38' User entered '16 Sep 2020 09:06'	System	16 Sep 2020 13:06:50
	System	16 Sep 2020 13:06:50

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 15:44:33

US3832176

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:58:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 15:44:33



US3832176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:31
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 18:12:42

US3832176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:31
User entered '16 Sep 2020'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 18:12:42

US3832176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:31
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 18:12:42

US3832176

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:31
User entered empty.	Alyssa-Kay Peay (b) (4)	16 Sep 2020 18:12:42

US3832176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:48:40
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	16 Sep 2020 18:12:34

US3832176

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	16 Sep 2020 18:12:34

US3832176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:45
User entered 'Yes (Y)'	Emma Partin (b) (4)	23 Sep 2020 19:16:04

US3832176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:45
User entered '23 Sep 2020'	Emma Partin (b) (4)	23 Sep 2020 19:16:04



US3832176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:45
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	23 Sep 2020 19:16:04

US3832176

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:45
User entered empty.	Emma Partin (b) (4)	23 Sep 2020 19:16:04

US3832176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:52
User entered 'Yes (Y)'	Emma Partin (b) (4)	23 Sep 2020 19:16:16

US3832176

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	23 Sep 2020 19:16:16

US3832176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:59
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:56:47

US3832176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:59
User entered '30 Sep 2020'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:56:47

US3832176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:59
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:56:47

US3832176

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:49:59
User entered empty.	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:56:47



US3832176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:03
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	30 Sep 2020 18:56:53

US3832176

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	30 Sep 2020 18:56:53

**US3832176**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:12
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 18:24:56

US3832176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:12
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 18:24:56

US3832176

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:12
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	07 Oct 2020 18:24:56

**US3832176**

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

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'VISIT3'	System	07 Oct 2020 18:24:56

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 18:28:32



**US3832176**

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

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '11:12'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '7 Oct 2020 11:12'	System	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '97.9' F	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered 'Oral (Oral)'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered empty.	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '70'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'bpm'	System	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '13'	Emma Partin (b) (4)	07 Oct 2020 18:28:32



US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'breaths/min'	System	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '99'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:26
User entered '68'	Emma Partin (b) (4)	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'mmHg'	System	07 Oct 2020 18:28:32

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21

US3832176

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21

US3832176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:18
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 18:28:42



US3832176

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:18
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 18:28:42

US3832176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:49
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 18:28:55

US3832176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:49
User entered '7 Oct 2020'	Emma Partin (b) (4)	07 Oct 2020 18:28:55

US3832176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:49
User entered '11:22'	Emma Partin (b) (4)	07 Oct 2020 18:28:55

US3832176

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered '7 Oct 2020 11:22'	System	07 Oct 2020 18:28:55

US3832176

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:20:26
DataPoint Verified.	(b) (4), (b) (6)	23 Dec 2020 23:50:54
User entered 'Yes (Y)'	Emma Partin (b) (4)	07 Oct 2020 18:28:59

**US3832176**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	07 Oct 2020 18:28:59

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 64'	System	12 Aug 2020 16:16:56



US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-13T13:03:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '48dcefba-7c85-48e7-a66a-29991eee9cba' User entered 'No (N)'	System	13 Oct 2020 17:03:34
	System	13 Oct 2020 17:03:34

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

Have you been exposed to someone with 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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-13T13:03:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '48dcefba-7c85-48e7-a66a-29991eee9cba' User entered 'No (N)'	System	13 Oct 2020 17:03:34
	System	13 Oct 2020 17:03:34

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-13T13:03:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '48dcefb8-7c85-48e7-a66a-29991eee9cba' User entered '13 Oct 2020 13:03:28'	System	13 Oct 2020 17:03:34
	System	13 Oct 2020 17:03:34

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '12 Oct 2020 00:01'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '16 Oct 2020 23:59'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 71'	System	12 Aug 2020 16:16:56

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-20T16:52:35', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f49f437f-ba72-42fc-9bd4-89dd09faf073'	System	20 Oct 2020 20:53:06
User entered 'No (N)'	System	20 Oct 2020 20:53:06

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

Have you been exposed to someone with 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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-20T16:52:52', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f49f437f-ba72-42fc-9bd4-89dd09faf073'	System	20 Oct 2020 20:53:06
User entered 'No (N)'	System	20 Oct 2020 20:53:06



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-20T16:53:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f49f437f-ba72-42fc-9bd4-89dd09faf073' User entered '20 Oct 2020 16:53:02'	System	20 Oct 2020 20:53:06
	System	20 Oct 2020 20:53:06

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '19 Oct 2020 00:01'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '23 Oct 2020 23:59'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 78'	System	12 Aug 2020 16:16:56

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-27T19:12:20', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '1913da8b-e325-4f01-bfbe-e0cf0b34947f' User entered 'No (N)'	System	27 Oct 2020 23:12:37
	System	27 Oct 2020 23:12:37

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

Have you been exposed to someone with 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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-10-27T19:12:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '1913da8b-e325-4f01-bfbe-e0cf0b34947f' User entered 'No (N)'	System	27 Oct 2020 23:12:37
	System	27 Oct 2020 23:12:37



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '26 Oct 2020 00:01'	System	12 Aug 2020 16:16:56



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '30 Oct 2020 23:59'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 92'	System	12 Aug 2020 16:16:56

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-09T14:25:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '547cbb62-0200-4b8b-9d53-349684bc6314' User entered 'No (N)'	System	09 Nov 2020 19:25:54
	System	09 Nov 2020 19:25:54

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

Have you been exposed to someone with 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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-09T14:25:45', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '547cbb62-0200-4b8b-9d53-349684bc6314' User entered 'No (N)'	System	09 Nov 2020 19:25:54
	System	09 Nov 2020 19:25:54

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-09T14:25:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '547cbb62-0200-4b8b-9d53-349684bc6314' User entered '09 Nov 2020 14:25:50'	System	09 Nov 2020 19:25:54
	System	09 Nov 2020 19:25:54

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '09 Nov 2020 00:01'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '13 Nov 2020 23:59'	System	12 Aug 2020 16:16:56

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered 'Day 99'	System	12 Aug 2020 16:16:56



US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

[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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-16T09:56:11', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'bd79a480-a6be-42f0-bed4-608fcbb12c10'	System	16 Nov 2020 14:56:41
User entered 'No (N)'	System	16 Nov 2020 14:56:41

US3832176

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:58:54

Have you been exposed to someone with 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 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-16T09:56:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'bd79a480-a6be-42f0-bed4-608fcbb12c10'	System	16 Nov 2020 14:56:41
User entered 'No (N)'	System	16 Nov 2020 14:56:41

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-16T09:56:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'bd79a480-a6be-42f0-bed4-608fcbb12c10' User entered '16 Nov 2020 09:56:39'	System	16 Nov 2020 14:56:41
	System	16 Nov 2020 14:56:41

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '16 Nov 2020 00:01'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:07:00
Data entry locked.	System	12 Aug 2020 16:16:56
User entered '20 Nov 2020 23:59'	System	12 Aug 2020 16:16:56

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-24T16:01:29', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51bc8eca-aa8c-4581-9189-0cd87559219a' User entered 'No (N)'	System	24 Nov 2020 21:01:55
	System	24 Nov 2020 21:01:55

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-24T16:01:43', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51bc8eca-aa8c-4581-9189-0cd87559219a' User entered 'No (N)'	System	24 Nov 2020 21:01:55
	System	24 Nov 2020 21:01:55



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-24T16:01:51', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '51bc8eca-aa8c-4581-9189-0cd87559219a' User entered '24 Nov 2020 16:01:51'	System	24 Nov 2020 21:01:55
	System	24 Nov 2020 21:01:55

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-29T15:51:02', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e200584b-eb3d-4182-98ac-2236b988dfa8' User entered 'No (N)'	System	29 Nov 2020 20:51:22

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-29T15:51:10', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e200584b-eb3d-4182-98ac-2236b988dfa8' User entered 'No (N)'	System	29 Nov 2020 20:51:22

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-11-29T15:51:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'e200584b-eb3d-4182-98ac-2236b988dfa8' User entered '29 Nov 2020 15:51:19'	System	29 Nov 2020 20:51:22
	System	29 Nov 2020 20:51:22

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-04T11:44:19', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5b652c6a-f963-4731-bd63-ed52312f1136'	System	04 Dec 2020 16:44:45
User entered 'No (N)'	System	04 Dec 2020 16:44:45

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-04T11:44:37', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5b652c6a-f963-4731-bd63-ed52312f1136'	System	04 Dec 2020 16:44:45
User entered 'No (N)'	System	04 Dec 2020 16:44:45

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-04T11:44:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5b652c6a-f963-4731-bd63-ed52312f1136' User entered '04 Dec 2020 11:44:41'	System	04 Dec 2020 16:44:45
	System	04 Dec 2020 16:44:45

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:53:53



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-11T10:22:10', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5419e191-752c-4197-804f-ff784e72ca96'	System	11 Dec 2020 15:22:46
User entered 'No (N)'	System	11 Dec 2020 15:22:46

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-11T10:22:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5419e191-752c-4197-804f-ff784e72ca96'	System	11 Dec 2020 15:22:46
User entered 'No (N)'	System	11 Dec 2020 15:22:46

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-11T10:22:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '5419e191-752c-4197-804f-ff784e72ca96' User entered '11 Dec 2020 10:22:41'	System	11 Dec 2020 15:22:46
	System	11 Dec 2020 15:22:46

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-18T14:52:30', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '84e3f19f-59cd-4133-b0d7-7b2c1eb9e606'	System	18 Dec 2020 20:52:45
User entered 'No (N)'	System	18 Dec 2020 20:52:45

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-18T14:52:32', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '84e3f19f-59cd-4133-b0d7-7b2c1eb9e606'	System	18 Dec 2020 20:52:45
User entered 'No (N)'	System	18 Dec 2020 20:52:45



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-18T14:52:39', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '84e3f19f-59cd-4133-b0d7-7b2c1eb9e606' User entered '18 Dec 2020 14:52:39'	System	18 Dec 2020 20:52:45
	System	18 Dec 2020 20:52:45

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-25T16:26:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '510ee9d3-3683-405d-b149-d562340ee3c6' User entered 'No (N)'	System	25 Dec 2020 22:27:13
	System	25 Dec 2020 22:27:13

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-25T16:27:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '510ee9d3-3683-405d-b149-d562340ee3c6'	System	25 Dec 2020 22:27:13
User entered 'No (N)'	System	25 Dec 2020 22:27:13

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2020-12-25T16:27:11', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '510ee9d3-3683-405d-b149-d562340ee3c6' User entered '25 Dec 2020 16:27:11'	System	25 Dec 2020 22:27:13
	System	25 Dec 2020 22:27:13

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:53:53

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:12:40', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered 'Yes (Y)'	System	01 Jan 2021 13:15:31
	System	01 Jan 2021 13:15:31

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:13:12', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea'	System	01 Jan 2021 13:15:31
User entered 'Yes (Y)'	System	01 Jan 2021 13:15:31

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:13:32', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea'	System	01 Jan 2021 13:15:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 13:15:31

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:13:45', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered 'Yes (Y)'	System	01 Jan 2021 13:15:31
	System	01 Jan 2021 13:15:31

**US3832176**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '0'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '0'	System	01 Jan 2021 13:15:31
	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '1'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '0'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '0'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea'	System	01 Jan 2021 13:15:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 13:15:31



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:48', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered 'Yes (Y)'	System	01 Jan 2021 13:15:31
	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:14:54', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea'	System	01 Jan 2021 13:15:31
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-01T08:15:22', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '06324fd7-653f-4a9c-aea5-78c5c51c9bea' User entered '01 Jan 2021 08:15:22'	System	01 Jan 2021 13:15:31
	System	01 Jan 2021 13:15:31

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-11T10:34:24', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0a20c60f-60d8-4a79-bfb7-6bada759b8b4' User entered 'No (N)'	System	11 Jan 2021 15:34:44
	System	11 Jan 2021 15:34:44

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-11T10:34:31', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0a20c60f-60d8-4a79-bfb7-6bada759b8b4'	System	11 Jan 2021 15:34:44
User entered 'No (N)'	System	11 Jan 2021 15:34:44



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-11T10:34:38', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '0a20c60f-60d8-4a79-bfb7-6bada759b8b4' User entered '11 Jan 2021 10:34:38'	System	11 Jan 2021 15:34:44
	System	11 Jan 2021 15:34:44

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-17T16:04:18', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4ef9ebce-5ad2-4882-a1e5-589b670b8c78'	System	17 Jan 2021 21:04:38
User entered 'No (N)'	System	17 Jan 2021 21:04:38

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-17T16:04:26', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4ef9ebce-5ad2-4882-a1e5-589b670b8c78'	System	17 Jan 2021 21:04:38
User entered 'No (N)'	System	17 Jan 2021 21:04:38

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-17T16:04:35', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4ef9ebce-5ad2-4882-a1e5-589b670b8c78' User entered '17 Jan 2021 16:04:35'	System	17 Jan 2021 21:04:38
	System	17 Jan 2021 21:04:38

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-23T08:22:16', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '353de77b-d45c-444b-807c-c1e949c26666'	System	23 Jan 2021 13:22:36
User entered 'No (N)'	System	23 Jan 2021 13:22:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-23T08:22:21', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '353de77b-d45c-444b-807c-c1e949c26666'	System	23 Jan 2021 13:22:36
User entered 'No (N)'	System	23 Jan 2021 13:22:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-23T08:22:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '353de77b-d45c-444b-807c-c1e949c26666' User entered '23 Jan 2021 08:22:33'	System	23 Jan 2021 13:22:36
	System	23 Jan 2021 13:22:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-29T16:41:01', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a4363e5a-65f4-4a67-8bc3-92ae62a85c99'	System	29 Jan 2021 21:41:17
User entered 'No (N)'	System	29 Jan 2021 21:41:17

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-29T16:41:08', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a4363e5a-65f4-4a67-8bc3-92ae62a85c99'	System	29 Jan 2021 21:41:17
User entered 'No (N)'	System	29 Jan 2021 21:41:17

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-01-29T16:41:14', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'a4363e5a-65f4-4a67-8bc3-92ae62a85c99' User entered '29 Jan 2021 16:41:14'	System	29 Jan 2021 21:41:17
	System	29 Jan 2021 21:41:17

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-05T14:09:04', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '6bc23e76-0bb0-4e8c-8d47-1539980b516b' User entered 'No (N)'	System	05 Feb 2021 19:09:22

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-05T14:09:12', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '6bc23e76-0bb0-4e8c-8d47-1539980b516b'	System	05 Feb 2021 19:09:22
User entered 'No (N)'	System	05 Feb 2021 19:09:22



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-05T14:09:18', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '6bc23e76-0bb0-4e8c-8d47-1539980b516b' User entered '05 Feb 2021 14:09:18'	System	05 Feb 2021 19:09:22
	System	05 Feb 2021 19:09:22

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-12T11:14:23', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ecf07d7a-26f4-4b43-99f0-3dab538871df' User entered 'No (N)'	System	12 Feb 2021 16:14:36
	System	12 Feb 2021 16:14:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-12T11:14:28', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ecf07d7a-26f4-4b43-99f0-3dab538871df' User entered 'No (N)'	System	12 Feb 2021 16:14:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-12T11:14:33', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'ecf07d7a-26f4-4b43-99f0-3dab538871df' User entered '12 Feb 2021 11:14:33'	System	12 Feb 2021 16:14:36
	System	12 Feb 2021 16:14:36

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-19T13:03:35', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3b488e40-7c00-4712-9d39-c21cf4a35f3b' User entered 'No (N)'	System	19 Feb 2021 18:07:09
	System	19 Feb 2021 18:07:09

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-19T13:03:41', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3b488e40-7c00-4712-9d39-c21cf4a35f3b' User entered 'No (N)'	System	19 Feb 2021 18:07:09
	System	19 Feb 2021 18:07:09

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-19T13:03:50', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3b488e40-7c00-4712-9d39-c21cf4a35f3b' User entered '19 Feb 2021 13:03:50'	System	19 Feb 2021 18:07:09
	System	19 Feb 2021 18:07:09

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-28T21:08:27-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '64b71432-3a44-47f8-b4a4-4c7be16420d5'	System	01 Mar 2021 02:19:44
User entered 'No (N)'	System	01 Mar 2021 02:19:44

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-28T21:08:31-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '64b71432-3a44-47f8-b4a4-4c7be16420d5'	System	01 Mar 2021 02:19:44
User entered 'No (N)'	System	01 Mar 2021 02:19:44

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-28T21:08:40-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '64b71432-3a44-47f8-b4a4-4c7be16420d5'	System	01 Mar 2021 02:19:44
User entered '01 Mar 2021 02:08:40'	System	01 Mar 2021 02:19:44

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:50:29-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered 'Yes (Y)'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:50:37-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered 'No (N)'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:50:43-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered 'No (N)'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:50:49-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered 'Yes (Y)'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:50:59-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-12T18:51:17-06:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'b3d2f884-e590-4086-9082-49b3d6ab2caf'	System	13 Mar 2021 00:51:29
User entered '12 Mar 2021 18:51:17'	System	13 Mar 2021 00:51:29

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:44:47-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered 'Yes (Y)'	System	21 Mar 2021 00:45:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:44:54-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered 'No (N)'	System	21 Mar 2021 00:45:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:45:01-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered 'No (N)'	System	21 Mar 2021 00:45:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:45:12-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered 'Yes (Y)'	System	21 Mar 2021 00:45:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:45:19-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 00:45:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-20T19:45:32-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '3e41cdf6-770b-4efb-9d64-b76e1967f6a5'	System	21 Mar 2021 00:45:43
User entered '20 Mar 2021 19:45:32'	System	21 Mar 2021 00:45:43



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-29T14:06:26-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'cdf255d3-b9ba-4842-9fb2-4f8c4bc39bc1'	System	29 Mar 2021 18:06:43
User entered 'No (N)'	System	29 Mar 2021 18:06:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-29T14:06:34-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'cdf255d3-b9ba-4842-9fb2-4f8c4bc39bc1'	System	29 Mar 2021 18:06:43
User entered 'No (N)'	System	29 Mar 2021 18:06:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-03-29T14:06:40-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'cdf255d3-b9ba-4842-9fb2-4f8c4bc39bc1'	System	29 Mar 2021 18:06:43
User entered '29 Mar 2021 14:06:40'	System	29 Mar 2021 18:06:43

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-02T14:20:57-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f31e9748-9331-4572-a202-2574f859be48'	System	02 Apr 2021 18:21:13
User entered 'No (N)'	System	02 Apr 2021 18:21:13

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-02T14:21:04-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f31e9748-9331-4572-a202-2574f859be48'	System	02 Apr 2021 18:21:13
User entered 'No (N)'	System	02 Apr 2021 18:21:13

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-02T14:21:08-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'f31e9748-9331-4572-a202-2574f859be48'	System	02 Apr 2021 18:21:13
User entered '02 Apr 2021 14:21:08'	System	02 Apr 2021 18:21:13

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-09T09:30:04-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '69178885-bca0-42fd-8aea-615177f14147'	System	09 Apr 2021 13:30:25
User entered 'No (N)'	System	09 Apr 2021 13:30:25



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-09T09:30:15-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '69178885-bca0-42fd-8aea-615177f14147'	System	09 Apr 2021 13:30:25
User entered 'No (N)'	System	09 Apr 2021 13:30:25

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-09T09:30:20-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '69178885-bca0-42fd-8aea-615177f14147'	System	09 Apr 2021 13:30:25
User entered '09 Apr 2021 09:30:20'	System	09 Apr 2021 13:30:25

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-16T18:19:17-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fee3fed8-6cfa-48c1-9c3c-3f2b980fbefb' User entered 'No (N)'	System	16 Apr 2021 22:19:38
	System	16 Apr 2021 22:19:38

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-16T18:19:22-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fee3fed8-6cfa-48c1-9c3c-3f2b980fbefb' User entered 'No (N)'	System	16 Apr 2021 22:19:38

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-16T18:19:32-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: 'fee3fed8-6cfa-48c1-9c3c-3f2b980fbefb' User entered '16 Apr 2021 18:19:32'	System	16 Apr 2021 22:19:38
	System	16 Apr 2021 22:19:38



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:08:43-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5'	System	25 Apr 2021 16:11:50
User entered 'Yes (Y)'	System	25 Apr 2021 16:11:50

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:10:07-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5'	System	25 Apr 2021 16:11:50
User entered 'No (N)'	System	25 Apr 2021 16:11:50

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:10:15-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5'	System	25 Apr 2021 16:11:50
User entered 'No (N)'	System	25 Apr 2021 16:11:50

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:10:28-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5'	System	25 Apr 2021 16:11:50
User entered 'Yes (Y)'	System	25 Apr 2021 16:11:50

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:10:41-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5'	System	25 Apr 2021 16:11:50
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 16:11:50



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-25T12:10:53-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '7d72e562-15fd-42af-a541-7a514b2e74c5' User entered '25 Apr 2021 12:10:53'	System	25 Apr 2021 16:11:50
	System	25 Apr 2021 16:11:50

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-30T16:20:37-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4af311f4-7de8-4777-af0c-6dc4923f63bb' User entered 'No (N)'	System	30 Apr 2021 20:20:57
	System	30 Apr 2021 20:20:57

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

Have you been exposed to someone with 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 (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-30T16:20:45-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4af311f4-7de8-4777-af0c-6dc4923f63bb' User entered 'No (N)'	System	30 Apr 2021 20:20:57

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-04-30T16:20:54-04:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '4af311f4-7de8-4777-af0c-6dc4923f63bb' User entered '30 Apr 2021 16:20:54'	System	30 Apr 2021 20:20:57
	System	30 Apr 2021 20:20:57

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:53:53



**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '07 Oct 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '11 Oct 2022 23:59'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '14 Oct 2022 00:01'	System	19 Nov 2020 04:53:53

**US3832176**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:58:54**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:53:53
Amendment Manager: User entered '18 Oct 2022 23:59'	System	19 Nov 2020 04:53:53

US3832176

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:58:54**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:37:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-28T21:08:50-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '918c0b79-0415-4cdd-88e1-a9e1dc9a052e'	System	01 Mar 2021 02:20:03
User entered 'No (N)'	System	01 Mar 2021 02:20:03

US3832176

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:58:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:37:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (62532C1C-03C9-427D-8547-E335E3647A3D)', Time: '2021-02-28T21:08:58-05:00', User OID: 'PatientReportedOutcome (US3832176)', ODM File OID: '918c0b79-0415-4cdd-88e1-a9e1dc9a052e' User entered '01 Mar 2021 02:08:58'	System	01 Mar 2021 02:20:03
	System	01 Mar 2021 02:20:03

US3832176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:06:57
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:15:39



US3832176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:06:57
User entered '4 Nov 2020'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:15:39

US3832176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:06:57
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:15:39

US3832176

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:06:57
User entered empty.	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:15:39

US3832176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:03
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	04 Nov 2020 15:15:43

US3832176

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 13:19:21
User entered 'I'	System	04 Nov 2020 15:15:43

US3832176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'please complete D149 visit in the EDC' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	25 Jan 2021 21:54:13
Query 'please complete D149 visit in the EDC' answered with 'Verified and updated.' (Site from CRA).	Rodolfo Barrera (b) (4)	25 Jan 2021 21:44:03
	(b) (4)	
User opened query 'please complete D149 visit in the EDC' (Site from CRA).	(b) (4), (b) (6)	25 Jan 2021 13:23:17
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 15:30:28
	(b) (4)	

US3832176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:51
User entered '9 Dec 2020'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 15:30:28

**US3832176**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:51
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 15:30:28



US3832176

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:51
User entered empty.	Alyssa-Kay Peay (b) (4)	09 Dec 2020 15:30:28

US3832176

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 00:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	09 Dec 2020 15:30:33

**US3832176**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User entered 'I'	System	09 Dec 2020 15:30:33

US3832176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	25 Jan 2021 21:43:29

US3832176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '8 Jan 2021'	Rodolfo Barrera (b) (4)	25 Jan 2021 21:43:29

US3832176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	25 Jan 2021 21:43:29

US3832176

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	Rodolfo Barrera (b) (4)	25 Jan 2021 21:43:29

US3832176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:54:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	25 Jan 2021 21:43:40



US3832176

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User entered 'I'	System	25 Jan 2021 21:43:40

**US3832176**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 19:59:37

**US3832176**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '8 Feb 2021'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 19:59:37

US3832176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 19:59:37

US3832176

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:12
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 19:59:37

US3832176

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:26:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Feb 2021 19:59:42

**US3832176**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:47:56
User entered 'I'	System	08 Feb 2021 19:59:42

US3832176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:27:08
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:27:39



US3832176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
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)	15 Apr 2021 15:25:12
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:51:15
User closed query 'Please confirm. All CRIO timestamps indicates 8Apr2021.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:50:56
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Noted as a PD' (Site from System).	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 15:14:33
Query 'Please confirm. All CRIO timestamps indicates 8Apr2021.' answered with 'data entry error' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 15:12:55
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	14 Apr 2021 15:12:22
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 15:12:22
User entered '08 Apr 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 15:12:22
User opened query 'Please confirm. All CRIO timestamps indicates 8Apr2021.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:29:09
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:28:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:27:08
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:12:54
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4) (b) (4)	16 Mar 2021 17:27:39

US3832176

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:27:08
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Clinic (Clinic)'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:27:39

**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	16 Mar 2021 17:27:39

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03



US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:33:03



US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:29:58
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered empty.	System	01 Apr 2021 15:33:03

US3832176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:30:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:27:46

US3832176

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:30:06
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Rodolfo Barrera (b) (4)	16 Mar 2021 17:27:46

US3832176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:52:41
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:28:10

US3832176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 08 APRIL 2021, as it is updated under V4D209 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 14:00:49
User opened query 'Per GCL Lab Recon:LB4 Immuno: There is a visit mismatch between EDC & GCL per latest Preclarus reports for this sample dated 08 APRIL 2021, as it is updated under V4D209 here in EDC, however in PPD GCL it is updated under OL-D57. Please kindly confirm which data is correct and update accordingly in EDC or Preclarus as necessary by sending a DCF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:55:12
User closed query 'Per Lab Recon: V4 D209: Immuno: Sample dated 11 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:53:32
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:52:41
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Apr 2021 15:20:31
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).		14 Apr 2021 15:20:31
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:20:31
User entered '08 Apr 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:20:31

US3832176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	14 Apr 2021 15:12:22
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
Query 'Per Lab Recon: V4 D209: Immuno: Sample dated 11 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' answered with 'Currently working with Perclaus to resolve.' (Site from DM).	(b) (4)	
	Danyel Johnson (b) (4)	02 Apr 2021 19:28:41
	(b) (4)	
User opened query 'Per Lab Recon: V4 D209: Immuno: Sample dated 11 MAR 2021, is still missing in PPD GCL records. Please confirm if the sample has been collected & shipped, if yes please kindly provide the Accession number, Tracking number, shipping date in response, as this helps to track the missing sample with the details provided. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 10:56:32
User entered '11 Mar 2021'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:28:10
	(b) (4)	

US3832176

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 19:06:35
User closed query 'Please confirm. Per source 10:41.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 19:06:21
Query 'Please confirm. Per source 10:41.' answered with 'Corrected ' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 16:06:02
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Apr 2021 16:05:49
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	14 Apr 2021 16:05:49
User entered '10:41' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:52:41
User opened query 'Please confirm. Per source 10:41.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:52:36
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
	(b) (4)	
User entered '10:20'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:28:10
	(b) (4)	



**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 10:41'	System	14 Apr 2021 16:05:49
User entered '08 Apr 2021 10:20'	System	14 Apr 2021 15:20:31
User entered '11 Mar 2021 10:20'	System	16 Mar 2021 17:28:10

US3832176

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 16:00:46
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	16 Mar 2021 17:28:17

**US3832176**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Mar 2021 17:28:17

**US3832176**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:52
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Apr 2021 18:28:29

US3832176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:52
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '8 Apr 2021'	Rodolfo Barrera (b) (4)	08 Apr 2021 18:28:29

US3832176

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:52
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	08 Apr 2021 18:28:29

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Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:56:52
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Rodolfo Barrera (b) (4)	08 Apr 2021 18:28:29

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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:01
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Apr 2021 18:28:36



**US3832176**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 18:28:36

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:35:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 23:09:39

**US3832176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:35:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '4 Jan 2021'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:09:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[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 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:35:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	06 Jan 2021 23:09:39

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'UNBLND_DECIDE'	System	06 Jan 2021 23:09:39

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	19 Feb 2021 16:47:10
User entered '6 Jan 2021'	(b) (4)	
	Emma Partin (b) (4)	06 Jan 2021 23:10:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:21:06

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 23:10:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User closed query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 01:09:32
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
Query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'Updated.' (Site from DM).	Rodolfo Barrera (b) (4)	08 Apr 2021 12:55:58
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 12:55:50
User opened query 'Per CDM, per Sponsor Review: IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 10:44:50
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:21:06

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '4 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Danyel Johnson (b) (4)	19 Feb 2021 16:47:10
User entered '6 Jan 2021'	(b) (4)	
	Emma Partin (b) (4)	06 Jan 2021 23:10:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Placebo (Placebo)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:22

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	
User entered 'Placebo (Placebo)'	System	20 Jan 2021 07:04:20
	Emma Partin (b) (4)	06 Jan 2021 23:10:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	
	System	20 Jan 2021 07:04:20
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	06 Jan 2021 23:10:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:41:55
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:22

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '1'	System	06 Jan 2021 23:10:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:58:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'I'	System	06 Jan 2021 23:10:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:16
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:32
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '65.0' in	Emma Partin (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:19
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:45
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:41
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '210.5' lb	Emma Partin (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered empty.	System	14 Apr 2021 15:09:59
User entered '35.10228'	System	06 Jan 2021 23:13:01
DataPoint set to visible.	System	06 Jan 2021 23:10:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:16
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:32
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '65.0' in	Emma Partin (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:19
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:45
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:41
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '210.5' lb	Emma Partin (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered empty.	System	14 Apr 2021 15:09:59
User entered '35.10228'	System	06 Jan 2021 23:13:01
DataPoint set to visible.	System	06 Jan 2021 23:10:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	
	System	19 Feb 2021 16:47:10
Amendment Manager: User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:48:08
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 23:13:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:04'	(b) (4)	
	Emma Partin (b) (4)	06 Jan 2021 23:13:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '4 Jan 2021 14:04'	System	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '98.2' F	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '86'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'bpm'	System	06 Jan 2021 23:13:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '13'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'breaths/min'	System	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '126'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '81'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:16
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:32
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '65.0' in	Emma Partin (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:54:21
User closed query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:19
Query 'Please confirm. Per source not done at OL-D1.' answered with 'Updated per review' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 15:10:45
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 15:09:59
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User opened query 'Please confirm. Per source not done at OL-D1.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:44:41
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '210.5' lb	Emma Partin (b) (4)	06 Jan 2021 23:13:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:58:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered empty.	System	14 Apr 2021 15:09:59
User entered '35.10228'	System	06 Jan 2021 23:13:01
DataPoint set to visible.	System	06 Jan 2021 23:10:22

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	
	System	19 Feb 2021 16:47:10
Amendment Manager: User opened query 'The Collection Date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:48:08
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 23:13:01
	(b) (4)	

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**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:56'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '4 Jan 2021 14:56'	System	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '97.9' F	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4)	
	Emma Partin (b) (4)	06 Jan 2021 23:13:01
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '75'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'bpm'	System	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '16'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'breaths/min'	System	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '114'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	06 Jan 2021 23:13:01

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:44:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '78'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:13:01



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	06 Jan 2021 23:13:01

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 23:11:05

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	
Amendment Manager: User opened query 'The physical examination date is before the Date of updated Informed Consent. Please review and reconcile.' (Site from System).	System	19 Feb 2021 16:47:10
User entered '4 Jan 2021'	System	17 Feb 2021 00:48:08
	Emma Partin (b) (4)	06 Jan 2021 23:11:05
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4)	
	Emma Partin (b) (4)	06 Jan 2021 23:10:55
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	Emma Partin (b) (4)	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mRNA-1273'	System	06 Jan 2021 23:10:55
DataPoint set to visible.	System	06 Jan 2021 23:10:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Start Date is prior to the Date of unblinding. Please review and provide any needed correction.' (Site from System).	(b) (4)	19 Feb 2021 16:47:10
User closed query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).	System	19 Feb 2021 16:47:10
Amendment Manager: User opened query 'Start Date is prior to updated ICF Date. Please verify and reconcile.' (Site from System).	System	17 Feb 2021 00:48:08
Amendment Manager: User opened query 'Start Date is prior to the Date of unblinding. Please review and provide any needed correction.' (Site from System).	System	17 Feb 2021 00:48:08
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 23:10:55
	(b) (4)	



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:23'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '4 Jan 2021 14:23'	System	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:45:17
User entered 'ONCE'	System	06 Jan 2021 23:10:55

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'INTRAMUSCULAR'	System	06 Jan 2021 23:10:55

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 23:09:56

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	(b) (4)	19 Feb 2021 16:47:10
Amendment Manager: User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:48:08
User entered '4 Jan 2021'	Emma Partin (b) (4)	06 Jan 2021 23:09:56
	(b) (4)	

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '13:46'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:09:56



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '4 Jan 2021 13:46'	System	06 Jan 2021 23:09:56

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	06 Jan 2021 23:10:06

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	(b) (4)	19 Feb 2021 16:47:10
Amendment Manager: User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	17 Feb 2021 00:48:08
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 06-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 04-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.	(b) (4), (b) (6)	16 Feb 2021 06:34:09
' (Site from DM).		
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 06-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 04-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.	Danyel Johnson (b) (4)	09 Feb 2021 21:20:55
' answered with 'UPDATED' (Site from DM).	(b) (4)	
User entered '4 Jan 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	09 Feb 2021 21:20:51
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab (Single): Sample dated 06-Jan-2021 is recorded under OL-D1 (1) visit in EDC, however the same is reported with date 04-Jan-2021 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else clarify, Thank you.	(b) (4), (b) (6)	09 Feb 2021 08:22:25
' (Site from DM).		

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '6 Jan 2021'	Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:06

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:58:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '13:40'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:06

**US3832176**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:58:54**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '4 Jan 2021 13:40'	System	09 Feb 2021 21:20:51
User entered '6 Jan 2021 13:40'	System	06 Jan 2021 23:10:06

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:46:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4) (b) (4)	06 Jan 2021 23:10:34

US3832176

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'I'	System	06 Jan 2021 23:10:34



US3832176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	12 Jan 2021 15:29:45

US3832176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '12 Jan 2021'	Emma Partin (b) (4)	12 Jan 2021 15:29:45

US3832176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4)	12 Jan 2021 15:29:45

US3832176

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:58:54

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	Emma Partin (b) (4)	12 Jan 2021 15:29:45

US3832176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Emma Partin (b) (4)	12 Jan 2021 15:29:49

US3832176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
User entered 'I'	System	12 Jan 2021 15:29:49

US3832176

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:34:57
User entered 'I'	System	12 Jan 2021 15:29:49
DataPoint set to visible.	System	12 Jan 2021 15:29:49

**US3832176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:58:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	01 Feb 2021 22:14:50



US3832176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:58:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '1 Feb 2021'	Danyel Johnson (b) (4)	01 Feb 2021 22:14:50

US3832176

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

[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 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:58:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	01 Feb 2021 22:14:50

**US3832176**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'OLD29'	System	01 Feb 2021 22:14:50

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User accepted default value 'Pre-Dose (PREDOSE)'	Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:08'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '1 Feb 2021 14:08'	System	01 Feb 2021 22:16:52



US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '98.1' F	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Oral (Oral)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '87'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'bpm'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '16'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'breaths/min'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '117'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52



US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '77'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User accepted default value 'Post-Dose (POSTDOSE)'	Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:51'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '1 Feb 2021 14:51'	System	01 Feb 2021 22:16:52



US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '98.2' F	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Oral (Oral)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	Danyel Johnson (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '68'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

**US3832176**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'bpm'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '16'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'breaths/min'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '118'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52



US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '80'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mmHg'	System	01 Feb 2021 22:16:52

US3832176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:01

US3832176

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:46
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:01

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

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 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:26



US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'mRNA-1273'	System	01 Feb 2021 22:17:26
DataPoint set to visible.	System	12 Jan 2021 15:29:49

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '1 Feb 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	01 Feb 2021 22:17:26

**US3832176**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:54**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '14:17'	Danyel Johnson (b) (4)	01 Feb 2021 22:17:26

**US3832176**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:58:54**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered '1 Feb 2021 14:17'	System	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Left Arm (LEFT ARM)'	Danyel Johnson (b) (4)	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:59:50
User entered 'ONCE'	System	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:58:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'INTRAMUSCULAR'	System	01 Feb 2021 22:17:26

US3832176

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:00:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	01 Feb 2021 22:17:31



**US3832176**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:58:54**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'I'	System	01 Feb 2021 22:17:31

**US3832176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:00:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	08 Feb 2021 17:10:56

**US3832176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:00:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered '8 Feb 2021'	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 17:10:56

**US3832176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:00:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	08 Feb 2021 17:10:56

**US3832176**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:58:54**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:00:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered empty.	(b) (4) Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 17:10:56

US3832176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User closed query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 08 APRIL 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 21:32:18
Query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 08 APRIL 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you. ' answered with 'Updated per review of source' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	19 Apr 2021 17:01:06
User opened query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 08 APRIL 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:59:53
Query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 25 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:59:33
User opened query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 25 MAR 2021 is recorded under OL- 3 visit in PPD GCL, however the same is missing in OL-D57 in EDC. Please review and update the sample data in EDC as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 13:59:08
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:02:57
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4) (b) (4)	08 Feb 2021 17:11:02

US3832176

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:58:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:13:50
User entered 'I'	System	08 Feb 2021 17:11:02

**US3832176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Apr 2021 17:01:30
	(b) (4)	



US3832176

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:58:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	26 Apr 2021 14:15:41
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'Will be noted as a PD' (Site from System).	Danyel Johnson (b) (4) (b) (4)	19 Apr 2021 17:02:38
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	19 Apr 2021 17:01:30
User entered '8 Apr 2021'	Danyel Johnson (b) (4) (b) (4)	19 Apr 2021 17:01:30

**US3832176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	19 Apr 2021 17:01:30
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:58:54**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	19 Apr 2021 17:01:30

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:02:47

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	



**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:02:47

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:02:47

US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:02:47



US3832176

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:58:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:47
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:58:54**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Apr 2021 17:02:47

**US3832176**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:58:54**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered 'No (N)'	Danyel Johnson (b) (4)	19 Apr 2021 17:02:55
	(b) (4)	

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Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:58:54

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered empty.	Danyel Johnson (b) (4)	19 Apr 2021 17:02:55
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:54**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	19 Apr 2021 17:03:31
	(b) (4)	

US3832176

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:58:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered '8 Apr 2021'	Danyel Johnson (b) (4)	19 Apr 2021 17:03:31
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:54**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered '10:41'	Danyel Johnson (b) (4)	19 Apr 2021 17:03:31
	(b) (4)	

**US3832176**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:58:54**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '8 Apr 2021 10:41'	System	19 Apr 2021 17:03:31



US3832176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:58:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 04:13:00
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:39:51
User closed query 'Per DM RQ: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 20:28:16
Query 'Per DM RQ: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Per review of source no noted changes in health status.' (Site from DM).	Danyel Johnson (b) (4)	19 Apr 2021 16:59:14
User opened query 'Per DM RQ: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:29:03
User closed query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:28:47

US3832176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:58:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:27:46
User closed query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	18 Apr 2021 06:12:51
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:55:25
DataPoint Un-verified.	Danyel Johnson (b) (4)	12 Apr 2021 12:05:39
Signature has been broken.	(b) (4) Danyel Johnson (b) (4)	12 Apr 2021 12:05:39
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Apr 2021 12:05:39
Query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Per review subject was seen at site for day 145 but did not require the visit for an medically attend visit subject was seen for OL day 0 visit.' (Site from DM).	Danyel Johnson (b) (4)	05 Apr 2021 14:53:08

US3832176

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:58:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Safety Follow-up Diary Day 145, Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 11:14:41
Query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Per review of source no medically attended visit occurred ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	02 Apr 2021 19:26:39
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'Pre review no Medically attended visit occurred' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	02 Apr 2021 19:25:54
User opened query 'Per DM CLR: Per Day 222 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 07:15:24

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:58:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 11:33:03
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 23:51:55
User entered 'No (N)'	Danyel Johnson (b) (4)	18 Nov 2020 16:42:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:26:28
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:22
User entered	System	13 Apr 2021 13:50:17
'USA-US100-2021-mRNA-1273-P301000011'		
User entered 'New'	(b) (4), (b) (6)	13 Apr 2021 13:50:17

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:29
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Diaphragmatic hernias, PT: Hiatus hernia, LLT: Paraesophageal hiatal hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:31:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 13:31:08
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:12:54
Data point term sent to Coder	System	12 Apr 2021 12:22:11
User entered 'Worsening of Paraesophageal Hernia'	Danyel Johnson (b) (4) (b) (4)	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:30
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:32
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38



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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:58:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:33
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

US3832176

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:36
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '02 Mar 2021'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:38
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	(b) (4)	12 Apr 2021 12:32:09
User entered empty; reason for change Data Entry Error	Danyel Johnson (b) (4)	12 Apr 2021 12:32:09
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	12 Apr 2021 12:21:38
User entered '18:30'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 12:32:09
User entered '02 Mar 2021 18:30'	System	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:41
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

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If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:43
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '03 Mar 2021'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:44
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 12:21:38



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:46
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Grade 4 (Grade 4)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Event first captured in source on 08APr2021. Please clarify why event was reported in the EDC on 12Apr2021 , outside of 24hrs reporting window. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:54:40
Query 'Event first captured in source on 08APr2021. Please clarify why event was reported in the EDC on 12Apr2021 , outside of 24hrs reporting window. Thank you! ' answered with 'Several issues within the EDC system error CODES 402/502. The system kept kicking the site out and would not save data' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 14:33:45
User opened query 'Event first captured in source on 08APr2021. Please clarify why event was reported in the EDC on 12Apr2021 , outside of 24hrs reporting window. Thank you! ' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 20:41:15
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:26:47
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'I'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '02 Mar 2021'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:42:18
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:17
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '08 Mar 2021'	(b) (4) Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 13:16:06
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:32:43
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:15
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:05:50
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 13:16:08
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:32:48
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'Updated ' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:18
	(b) (4)	
DataPoint Un-verified.	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
	(b) (4)	
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
	(b) (4)	
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:06:09
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 13:16:10
User closed query 'PV Query: As the last dose of study drug was given on 01 Feb 2021, please update the action taken from none to not applicable. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:32:55
Query 'PV Query: As the last dose of study drug was given on 01 Feb 2021, please update the action taken from none to not applicable. Please update EDC accordingly.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:20
DataPoint Un-verified.	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	21 Apr 2021 13:20:12
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 01 Feb 2021, please update the action taken from none to not applicable. Please update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:05:32
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'None (NONE)'	(b) (4)	
	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38



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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'I'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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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)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please assess whether event atrial fibrillation should be reported as an SAE. If yes, please update the EDC, as needed, and if no, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 16:10:10
Query 'PV Query: Please assess whether event atrial fibrillation should be reported as an SAE. If yes, please update the EDC, as needed, and if no, please state so. ' answered with 'Per it was not a cause for hospitalization and per review does not meet the criteria for an SAE.' (Site from Safety).	Danyel Johnson (b) (4)	30 Apr 2021 12:42:26
User opened query 'PV Query: Please assess whether event atrial fibrillation should be reported as an SAE. If yes, please update the EDC, as needed, and if no, please state so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:44:36
User closed query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:33:35
User closed query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional 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)	22 Apr 2021 11:33:27
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:33:21
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 11:33:06

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Records sent 4/21/2021' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:22:00
Query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional 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' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:51
Query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Records sent 4/21/2021' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:39
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 'Testing not completed' (Site from Safety).	Danyel Johnson (b) (4)	21 Apr 2021 13:21:22
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:07:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:58:54

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any additional treatment given for the event including medical intervention and/or surgical treatments. Please add any additional 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)	20 Apr 2021 17:06:50
User opened query 'PV Query: Please provide any other relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 17:06:38
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)	20 Apr 2021 17:06:26
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '75 y/o female vaccinated 1/4/2021 last dose of IP 2/1/2021 with a history of hypertension, paraoesophageal hernia, breast cancer (lumpectomy and radiation) was seen on 3/2/2021 at the emergency room in (b) (6) and admitted while visiting her daughter after experiencing sever abdominal pain with nausea and vomiting that started 3/1/2021 around 1830. Subject had a CT scan which showed a large type 4 paraoesophageal hernia with most of the stomach in the chest on the left side and a portion of the transverse colon. Duodenum was noted to pulled up also into the portion of the hernia. No noted Ischemia on CT scan. Subject was scheduled for a robotic assisted paraoesophageal hernia repair with Nissen fundoplication on 3/3/2021. Subject remained in the hospital until 3/8/2021 for post-operative care.'	Danyel Johnson (b) (4)	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 12:21:38



**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 12:21:38

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 12:21:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:08
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 12:35:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 12:35:59
Data point term sent to Coder	System	12 Apr 2021 12:35:20
User entered 'Atrial Fibrillation'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:11
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:13
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:15
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:17
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '02 Mar 2021'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:56:20
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'No (N)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07



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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07



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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Not Applicable (NOT APPLICABLE)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Not Related (NOT RELATED)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'None (NONE)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'I'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 09:58:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '0'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:57:12
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	Danyel Johnson (b) (4)	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	12 Apr 2021 12:35:07

**US3832176**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 12:35:07

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:25
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:27:43
User entered	System	27 Apr 2021 15:27:34
'USA-US100-2021-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	27 Apr 2021 15:27:34

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:27
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 18:25:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Apr 2021 18:25:54
Data point term sent to Coder	System	26 Apr 2021 18:24:38
User entered 'Vertigo'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:31
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:34
User entered 'No (N)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:36
User entered 'No (N)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:44
User entered '22 Apr 2021'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:24:47
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:23:47

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:25:10
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:25:12
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:25:13
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:23:47



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:03:19
User closed query 'Please review source and revise if needed. Source states that AE was a Grade 4.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 15:03:08
Query 'Please review source and revise if needed. Source states that AE was a Grade 4.' answered with 'Corrected per review' (Site from CRA).	Danyel Johnson (b) (4)	29 Apr 2021 10:56:22
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4)	29 Apr 2021 10:56:09
User opened query 'Please review source and revise if needed. Source states that AE was a Grade 4.' (Site from CRA).	(b) (4), (b) (6)	28 Apr 2021 20:25:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:26:36
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Apr 2021 18:28:22
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	26 Apr 2021 18:23:47
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:26:39
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:26:44
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 19:41:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 20:26:46
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Data is correct as reported ' (Site from System).	Danyel Johnson (b) (4)	26 Apr 2021 18:29:21
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	26 Apr 2021 18:28:22
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:03:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Apr 2021 18:28:22
User entered '23 Apr 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	26 Apr 2021 18:23:47
User entered '23 ' (non-conformant).	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Generated On: 10 Jun 2021 09:58:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered '25 Apr 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	



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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:32
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:28:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 18:28:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Apr 2021 18:23:47
	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:33
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:28:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 18:28:22
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	26 Apr 2021 18:23:47
	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:34
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:28:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 18:28:22
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:23:47
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

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Generated On: 10 Jun 2021 09:58:54

None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:41
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Apr 2021 18:28:22
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	26 Apr 2021 18:23:47
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	



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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:42
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
	(b) (4)	
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:44
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 09:58:54

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 20:27:49
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:28:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Apr 2021 18:28:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Apr 2021 18:23:47
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:03:35
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 18:40:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 15:04:10
User entered 'Subject contacted after her diary indicated a change in health status. Per subject she was admitted 4/23/2021 after experiencing vertigo subject was discharged 4/25/2021 with Antivert 25mg PRN. Records release sent to subject to obtain all information for course of treatment while hospitalized.' reason for change: Data Entry Error	Danyel Johnson (b) (4)	26 Apr 2021 18:28:22
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	26 Apr 2021 18:23:47
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Apr 2021 18:23:47

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 18:23:47

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:58:54

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:32
User closed query 'Please update to include eliquis per source.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 16:02:03
Query 'Please update to include eliquis per source.' answered with 'Updated per review ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:40:48
User opened query 'Please update to include eliquis per source.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:47:46
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 21:39:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:11



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:31:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 12:31:21
Data point term sent to Coder	System	12 Aug 2020 16:09:07
User entered 'Pantotrazole'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:01:51
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:01:08
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:57:26
User entered 'Gastroesophageal reflux disease'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '40'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:01
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	12 Aug 2020 16:16:56
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:08:44
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:08:44

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:08:44



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:08:44

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:08:44

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:10:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:10:16
Data point term sent to Coder	System	12 Aug 2020 16:09:07
User entered 'Losartan'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:12
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	12 Aug 2020 16:16:56
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:09:06
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:06

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:09:06

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:09:06

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:09:06

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:18:46
User closed query 'please spell out hydrochlorothiazide' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:18:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:12:56
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Dec 2020 16:12:56
	(b) (4)	
Query 'please spell out hydrochlorothiazide' answered with 'UPDATED' (Site from CRA).	Danyel Johnson (b) (4)	14 Dec 2020 16:12:43
	(b) (4)	
Data point term sent to Coder	System	14 Dec 2020 16:12:30
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Dec 2020 16:12:24
	(b) (4)	
Coding entries removed.	Danyel Johnson (b) (4)	14 Dec 2020 16:12:24
	(b) (4)	
User entered 'Hydrochlorothiazide' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Dec 2020 16:12:24
	(b) (4)	
User opened query 'please spell out hydrochlorothiazide' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 19:11:50
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE, PRODUCTSYNONYM: HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:11:07
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:11:07
	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 16:10:13
User entered 'HCTZ'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:09:32
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '25'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:20
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	12 Aug 2020 16:16:56
User entered 'un UNK 2000'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:09:32
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:09:32

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:09:32

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:09:32

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:09:32

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
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: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:12:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:12:13
Data point term sent to Coder User entered 'Amlodipine'	System Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:15 12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '2.5'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:54**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:27
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	12 Aug 2020 16:16:56
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:10:18
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:18

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:10:18

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:10:18

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:10:18



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: ESCITALOPRAM OXALATE, PRODUCTSYNONYM: LEXAPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:01:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:01:17
Data point term sent to Coder	System	12 Aug 2020 16:11:14
User entered 'Lexapro'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '10'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:39
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	12 Aug 2020 16:16:56
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:10:40
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:10:40

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:10:40



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:10:40

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:10:40

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CILOSTAZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 20:09:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 20:09:31
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 20:08:27
Coding entries removed.	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:07:34
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CILOSTAZOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 16:57:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 16:57:26
	(b) (4)	
Data point term sent to Coder	System	12 Aug 2020 16:12:16
User entered 'Cilostazol'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:11:27
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:30:51
Query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the MH eCRF.' answered with 'Reviewed an updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:55:33
User opened query 'Per DM CLR: Please note that there is no ongoing MH condition that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:48:55
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than BLOOD CIRCULATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:05:37
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than BLOOD CIRCULATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:07:52
User entered 'Peripheral Arterial Disease' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:07:34

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat, rather than BLOOD CIRCULATION. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:57:55
User entered 'Blood Circulation'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:11:27
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:47
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	12 Aug 2020 16:16:56
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:11:27
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:27

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 16:11:27

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:11:27

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:11:27

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:13:07
Data point term sent to Coder	System	12 Aug 2020 16:12:16
User entered 'Famotidine'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 20:10:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 20:10:04
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:10:04
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Aug 2020 16:11:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:05:46
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:10:14
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:58:31
User entered 'Gastroesophageal reflux disease'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:05:48
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:10:21
User entered '20' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:58:20
User entered '200'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:11:56
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:57:56
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	12 Aug 2020 16:16:56
User entered 'un UNK 2020'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:11:56
	(b) (4)	



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:11:56

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:11:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:11:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Aug 2020 16:11:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Aug 2020 16:14:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	12 Aug 2020 16:14:12
Data point term sent to Coder	System	12 Aug 2020 16:13:16
User entered 'Aspirin'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:12:21
	(b) (4)	



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Cardiac Prophylaxis'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '81'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:58:04
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	12 Aug 2020 16:16:56
User entered 'un UNK 2000'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:12:21
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:21

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:12:21

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:12:21



**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:12:21

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:17:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 20:17:42
Data point term sent to Coder Coding entries removed.	System Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:16:43 22 Oct 2020 20:15:57
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)	12 Aug 2020 16:14:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 16:14:12
Data point term sent to Coder User entered 'Tylenol'	System Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:13:18 12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:06:10
Query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:16:11
User entered 'GENERAL MYALGIA' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 20:15:57
User opened query 'Per DM CLR: Note there is no Medical History Condition or AE that matches this Con Med indication. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 07:58:56
User entered 'General Pain'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:12:48
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '1000'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
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)	13 Aug 2020 14:58:11
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	12 Aug 2020 16:16:56
User entered 'un UNK 2011'	Alyssa-Kay Peay (b) (4)	12 Aug 2020 16:12:48
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	12 Aug 2020 16:12:48



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	12 Aug 2020 16:12:48

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Aug 2020 16:12:48

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Aug 2020 16:12:48

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:48:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:48:45
Data point term sent to Coder	System	24 Feb 2021 13:17:01
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:16:06
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:34:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 21:34:49
Data point term sent to Coder	System	05 Feb 2021 14:59:02
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:58:38
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 22:46:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Dec 2020 22:46:22
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:28:28
Data point term sent to Coder	System	14 Dec 2020 16:20:39

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User closed query 'CDM Coding: The combined medication is not referenced in the standard dictionary. If not marketed as a combo, please split and report separately, one drug per line, to capture coding for all of them. Thank you.' (Site from System).	System	14 Dec 2020 16:20:30
Query 'CDM Coding: The combined medication is not referenced in the standard dictionary. If not marketed as a combo, please split and report separately, one drug per line, to capture coding for all of them. Thank you.' answered with 'UPDATED AND SEPARTED ' (Site from System).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:20:30
Data point term sent to Coder	System	14 Dec 2020 16:14:35
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:14:20
User entered 'PREDNISONE 1%' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:14:20
User opened query 'CDM Coding: The combined medication is not referenced in the standard dictionary. If not marketed as a combo, please split and report separately, one drug per line, to capture coding for all of them. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 11:54:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	13 Nov 2020 22:07:56
Data point term sent to Coder	System	22 Oct 2020 20:18:47
Coding entries removed.	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:17:47
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS AND ANTIINFECTIVES IN COMBINATION, ATC: CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION, PRODUCT: CORTICOSTEROIDS AND ANTIINFECTIVES IN COMBINATION - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:50:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Sep 2020 06:50:35
Data point term sent to Coder	System	02 Sep 2020 12:21:54

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Prednisone, Amoxifloxacin, Bronferiac Mix Drops'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:06
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 13:16:06
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 13:16:06
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:21:49
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:11
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:57:49
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:16:25
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:16:06
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:16:06
User entered 'Left Eye POST CATARACT SURGERY Infection preventive' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:16:06
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:36:46
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Cataract Surgery - Left Eye'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'I'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'drop'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:31:28
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:59:00
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:58:38
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:58:38
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 13:59:35
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Topical (TOPICAL)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:17:47
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Per CDM: "Route of administration" is Other and "If route of administration is Other, specify" is recorded as "DROP", which is not appropriate. Please update this field with appropriate of route through which the medication is being administered (Like: Intraocular, it is an option at "Route of administration"). Else clarify' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:06:25
Query 'Per CDM: "Route of administration" is Other and "If route of administration is Other, specify" is recorded as "DROP", which is not appropriate. Please update this field with appropriate of route through which the medication is being administered (Like: Intraocular, it is an option at "Route of administration"). Else clarify' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:18:20
	(b) (4)	
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	22 Oct 2020 20:17:47
	(b) (4)	
User opened query 'Per CDM: "Route of administration" is Other and "If route of administration is Other, specify" is recorded as "DROP", which is not appropriate. Please update this field with appropriate of route through which the medication is being administered (Like: Intraocular, it is an option at "Route of administration"). Else clarify' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 12:36:56
User entered 'drop'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:21:49
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '31 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:23
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'please confirm if ongoing.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:19:36
Query 'please confirm if ongoing.' answered with 'DATA REVIEWED AND UPDATED PER SUBJECT REPORT' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:20:57
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:20:11
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:20:11
User opened query 'please confirm if ongoing.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 18:52:06
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:48:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'source CM log reports med is ongoing. please reconcile.' (Site from CRA).	(b) (4)	
Query 'source CM log reports med is ongoing. please reconcile.' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:42:44
User opened query 'source CM log reports med is ongoing. please reconcile.' (Site from CRA).	Danyel Johnson (b) (4)	05 Feb 2021 14:59:02
DataPoint Un-verified.	(b) (4)	
User entered '10 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:22:43
DataPoint Verified.	Danyel Johnson (b) (4)	14 Dec 2020 16:20:11
User entered empty.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 16:20:11
	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:21:49
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:21:49

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	02 Sep 2020 12:21:49

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Sep 2020 12:21:49

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Sep 2020 12:21:49

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 16:15:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder Coding entries removed.	System	13 Nov 2020 16:15:01
	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:14:52
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:21:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	07 Oct 2020 15:18:43
User entered 'Influenza Vaccine'	Ashten Sheriff (b) (4)	07 Oct 2020 15:18:38
	(b) (4)	



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:48:37
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:56
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:15:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:14:52
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 09:59:52
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'INFLUENZA PROPHYLACTIC' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:14:52
User entered 'Influenza Vaccination'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '.5' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	13 Nov 2020 16:14:52
User entered '1'	(b) (4) Ashten Sheriff (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mL (mL)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:14:52
User entered 'Other (OTHER)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Nov 2020 16:14:52
User entered 'Injection'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'once (ONCE)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Intramuscular (INTRAMUSCULAR)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '07 Oct 2020'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '07 Oct 2020'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:18:38

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:18:38

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:18:38



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:18:38

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:46:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 15:46:11
Data point term sent to Coder	System	07 Oct 2020 15:21:53
User entered 'Meclizine'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Seasonal Allergies'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '10'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'as needed (PRN)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'UN UNK 1970'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 15:21:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Oct 2020 15:21:09
User entered 'No (N)' reason for change: Data Entry Error	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:09
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Oct 2020 15:21:01
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:21:01



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:21:01

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:21:01

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:21:01

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 22:07:56
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Oct 2020 15:24:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	07 Oct 2020 15:24:15
Data point term sent to Coder	System	07 Oct 2020 15:22:56
User entered 'Benadryl'	Ashten Sheriff (b) (4)	07 Oct 2020 15:22:08
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Seasonal Allergies'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '25'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'mg (mg)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'as needed (PRN)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Oral (ORAL)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'UN UNK 1970'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered '0'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'Yes (Y)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered empty.	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:56
User entered 'No (N)'	Ashten Sheriff (b) (4) (b) (4)	07 Oct 2020 15:22:08

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:22:08

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:22:08

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 15:22:08

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC SODIUM, PRODUCTSYNONYM: BROMFENAC OPHTHALMIC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 05:31:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 05:31:53
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 15:58:00
User closed query 'Please confirm. Strength not noted in source.' (Site from CRA).	(b) (4), (b) (6)	14 Apr 2021 15:57:56
Query 'Please confirm. Strength not noted in source.' answered with 'Source updated' (Site from CRA).	Danyel Johnson (b) (4)	14 Apr 2021 14:40:02
Data point term sent to Coder	System	14 Apr 2021 14:37:38
Coding entries removed.	Danyel Johnson (b) (4)	14 Apr 2021 14:36:42
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	14 Apr 2021 14:36:42
User entered 'Bromfenac ophthalmic solution 0.075%' reason for change: Data Entry Error	Danyel Johnson (b) (4)	14 Apr 2021 14:36:42
User opened query 'Please confirm. Strength not noted in source.' (Site from CRA).	(b) (4), (b) (6)	13 Apr 2021 17:52:15
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:41
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:23:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 14:23:44
Data point term sent to Coder	System	24 Feb 2021 13:19:02
Coding entries removed.	Danyel Johnson (b) (4)	24 Feb 2021 13:18:49
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Feb 2021 15:00:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 15:00:43
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4)	05 Feb 2021 15:00:02 05 Feb 2021 14:59:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:06
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFECTIVES, ATC: FLUOROQUINOLONES, PRODUCT: MOXIFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 14:50:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 14:50:46
Data point term sent to Coder User entered 'MOXIFLOXACIN 0.5%'	System Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:18:36 14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:08
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
DataPoint Un-verified.	Danyel Johnson (b) (4)	24 Feb 2021 13:18:49
Signature has been broken.	Danyel Johnson (b) (4)	24 Feb 2021 13:18:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	24 Feb 2021 13:18:49
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:24:10
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Dec 2020 16:17:56



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:04
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:56:53
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:18:56
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:18:49
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:18:49
User entered 'POST CATARACT SURGERY INFECTION PREVENTIVE' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:18:49
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:37:16
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:24:16
User entered 'CATARACT SURGERY'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:13
User entered 'I'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:19
User entered 'Other (OTHER)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:21
User entered 'dROP'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 17:43:25
User closed query 'per source, 3 time/day. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:43:22
Query 'per source, 3 time/day. please confirm and update' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4)	05 Feb 2021 15:00:27
	(b) (4)	
User entered 'three times daily (TID)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	05 Feb 2021 14:59:55
	(b) (4)	
User opened query 'per source, 3 time/day. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:28:08
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:27:57
	(b) (4), (b) (6)	22 Dec 2020 17:24:24
DataPoint Verified.	(b) (4)	
User entered 'twice daily (BID)'	Danyel Johnson (b) (4)	14 Dec 2020 16:17:56
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:29
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:51:00
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:32:28
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 15:00:25
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:59:55
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 14:59:55
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 19:56:31
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:24:27
User entered 'Topical (TOPICAL)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:54**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:32
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:34
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:38
User entered '0'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:54
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Dec 2020 16:17:56

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:50:56
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'per source con med log, med is ongoing. Please reconcile' (Site from CRA).	(b) (4)	
Query 'per source con med log, med is ongoing. Please reconcile' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:43:35
User opened query 'per source con med log, med is ongoing. Please reconcile' (Site from CRA).	Danyel Johnson (b) (4)	05 Feb 2021 15:00:23
User entered '10 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:25:08
	Danyel Johnson (b) (4)	14 Dec 2020 16:17:56
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:12
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:17:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Feb 2021 14:59:55
User entered '2'	System	14 Dec 2020 16:17:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:17:56

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 16:17:56



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:30:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Feb 2021 12:30:50
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:20:02 24 Feb 2021 13:19:19
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:09:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:09:52
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 15:01:04 05 Feb 2021 15:00:54
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:26:08
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: ANTIINFLAMMATORY AGENTS, NON-STEROIDS, PRODUCT: BROMFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 17:28:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 17:28:54
Data point term sent to Coder	System	14 Dec 2020 16:19:38
User entered 'BROMFENAC 0.075%'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:28
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 13:19:19
Signature has been broken.	(b) (4)	
	Danyel Johnson (b) (4)	24 Feb 2021 13:19:19
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:26:11
User entered 'No (N)'	Danyel Johnson (b) (4)	14 Dec 2020 16:19:35
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:26
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:10:33
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 17:57:13
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:19:32
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:19:19
Signature has been broken.	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:19:19
User entered 'POST CATARACT SURGERY INFECTION PREVENTIVE' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	24 Feb 2021 13:19:19
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 23:37:42
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:26:14
User entered 'CATRACT SURGERY'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'per source, 1 drop. please confirm and update.' (Site from CRA).	(b) (4)	08 Feb 2021 17:44:31
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 17:43:46
Query 'per source, 1 drop. please confirm and update.' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:43:46
User entered '1' reason for change: Data Entry Error	Danyel Johnson (b) (4)	05 Feb 2021 15:01:21
User opened query 'per source, 1 drop. please confirm and update.' (Site from CRA).	(b) (4)	05 Feb 2021 15:00:54
User entered '2'	(b) (4), (b) (6)	22 Dec 2020 17:26:47
	Danyel Johnson (b) (4)	14 Dec 2020 16:19:35
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 17:43:52
User entered 'Other (OTHER)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:50
User entered 'DROPS'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Feb 2021 17:43:58
User closed query 'per source, 3 time/day. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:43:55
Query 'per source, 3 time/day. please confirm and update' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4)	05 Feb 2021 15:01:19
User entered 'three times daily (TID)' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 15:00:54
DataPoint Un-verified.	(b) (4), (b) (6)	22 Dec 2020 17:27:41
User opened query 'per source, 3 time/day. please confirm and update' (Site from CRA).	(b) (4), (b) (6)	22 Dec 2020 17:27:37
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:25:52
User entered 'twice daily (BID)'	Danyel Johnson (b) (4)	14 Dec 2020 16:19:35
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:54
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 05:33:37
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 15:01:17
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 15:00:54
User entered 'Intraocular (INTRAOCULAR)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	05 Feb 2021 15:00:54
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 19:56:52
DataPoint Verified.	(b) (4), (b) (6)	22 Dec 2020 17:25:57
User entered 'Topical (TOPICAL)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:26:03
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:27:47
User entered '31 Aug 2020'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:42
User entered '0'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:45
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:19:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Dec 2020 16:19:41
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:41
User opened query 'Data is required. Please complete.' (Site from System).	System	14 Dec 2020 16:19:35
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 17:52:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
User closed query 'per source con med log, med is ongoing. Please reconcile' (Site from CRA).	(b) (4)	
Query 'per source con med log, med is ongoing. Please reconcile' answered with 'Reviewed and updated' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 17:44:05
User opened query 'per source con med log, med is ongoing. Please reconcile' (Site from CRA).	Danyel Johnson (b) (4)	05 Feb 2021 15:01:28
User entered '10 Sep 2020'	(b) (4)	
	(b) (4), (b) (6)	22 Dec 2020 17:25:28
	Danyel Johnson (b) (4)	14 Dec 2020 16:19:35
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:36
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 16:19:35

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	05 Feb 2021 15:00:54
User entered '2'	System	14 Dec 2020 16:19:35



US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Dec 2020 16:19:35

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Dec 2020 16:19:35

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:58:10
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:43:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 14:43:48
	(b) (4)	
Data point term sent to Coder	System	14 Apr 2021 14:42:42
User entered 'Eliquis'	Danyel Johnson (b) (4)	14 Apr 2021 14:42:24
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:12
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:23
User entered 'Atrial fibrillation'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:26
User entered '5'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:29
User entered 'mg (mg)'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:33
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 15:58:36
User entered 'once daily (QD)'	Danyel Johnson (b) (4)	14 Apr 2021 14:42:24
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:39
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:44
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:47
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:50
User entered '2 Mar 2021'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:54
User entered '0'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:58:57
User entered 'Yes (Y)'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:59:01
User entered empty.	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 15:59:05
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	14 Apr 2021 14:42:24

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 14:42:24

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Apr 2021 14:42:24

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	14 Apr 2021 14:42:24

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE HYDROCHLORIDE, PRODUCTSYNONYM: ANTIVERT [MECLOZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 18:33:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Apr 2021 18:33:07
Data point term sent to Coder	System	26 Apr 2021 18:32:04
User entered 'Antivert'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'No (N)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'Vertigo'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered '25'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'mg (mg)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'as needed (PRN)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'Oral (ORAL)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:40:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 19:31:36
User closed query 'Please review source and revise if needed. Source states that the start date was 22Apr2021.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 19:31:12
Query 'Please review source and revise if needed. Source states that the start date was 22Apr2021.' answered with 'Corrected per source' (Site from CRA).	Danyel Johnson (b) (4)	29 Apr 2021 18:38:26
	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	29 Apr 2021 18:37:49
	(b) (4)	
User entered '22 Apr 2021' reason for change: Data Entry Error	Danyel Johnson (b) (4)	29 Apr 2021 18:37:49
	(b) (4)	
User opened query 'Please review source and revise if needed. Source states that the start date was 22Apr2021.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 15:08:37
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 15:07:57
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
	(b) (4)	
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
User entered '23 Apr 2021'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55
	(b) (4)	

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered '0'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55



US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered empty.	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:58:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:04:36
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
User entered 'No (N)'	Danyel Johnson (b) (4)	26 Apr 2021 18:31:55

**US3832176**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:54**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:31:55

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:31:55

US3832176

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:58:54**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Apr 2021 18:31:55

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:58:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 09:04:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:06:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:21:55

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
Signature has been broken.	Danyel Johnson (b) (4)	14 Apr 2021 15:09:08
	(b) (4)	
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:02
User entered '31 Aug 2020'	Alyssa-Kay Peay (b) (4)	02 Sep 2020 12:22:15
	(b) (4)	



US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:02
User entered 'Cataract Surgery - Left Eye'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:22:15

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: For CATARACT SURGERY - LEFT EYE- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 08:49:36
Query 'Per CDM: For CATARACT SURGERY - LEFT EYE- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' answered with 'Condition noted in medical history ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	12 Mar 2021 16:27:15
User opened query 'Per CDM: For CATARACT SURGERY - LEFT EYE- indication is recorded as Medical History, Please review and update the indication as this is not recorded on Medical History page. Thank you ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 12:41:26
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 22:07:02
User closed query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:53:58
Query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	22 Oct 2020 20:24:33
User opened query 'Per DM CLR: Indication = Medical History, however, there is no corresponding medical condition recorded for this procedure in the MedHistory eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 11:47:08
User entered 'Medical History (MH)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:22:15

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:58:54

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 17:16:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 22:07:02
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Sep 2020 12:22:15

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:54

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:19:38
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered '03 Mar 2021'	(b) (4) Danyel Johnson (b) (4) (b) (4)	12 Apr 2021 12:36:19

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:19:40
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Robotic assisted paraoesophageal hernia repair'	(b) (4) Danyel Johnson (b) (4) (b) (4)	12 Apr 2021 12:36:19

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:19:41
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered 'Adverse Event (AE)'	(b) (4) Danyel Johnson (b) (4) (b) (4)	12 Apr 2021 12:36:19

US3832176

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:58:54

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:40:36
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:19:42
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:12:54
User entered empty.	(b) (4) Danyel Johnson (b) (4) (b) (4)	12 Apr 2021 12:36:19

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:36
User entered	System	13 Apr 2021 13:50:17
'USA-US100-2021-MRNA-1273-P301000011'		



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Gowdhami'	System	13 Apr 2021 13:50:17



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Mohan'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '1655 E. Greenville St'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Anderson'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'SC'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '29621'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered 'US'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 16:13:43
User entered '2'	System	22 Apr 2021 13:30:27
User entered '1'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:36
User entered	System	13 Apr 2021 13:50:17
'USA-US100-2021-MRNA-1273-P301000011'		



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Gowdhami'	System	13 Apr 2021 13:50:17



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Mohan'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '1655 E. Greenville St'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Anderson'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'SC'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '29621'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered 'US'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 16:13:43
User entered '2'	System	22 Apr 2021 13:30:27
User entered '1'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered '13/Apr/2021 09:50'	System	13 Apr 2021 13:50:48



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:58:54

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:36
User entered	System	13 Apr 2021 13:50:17
'USA-US100-2021-MRNA-1273-P301000011'		

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Gowdhami'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Mohan'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '1655 E. Greenville St'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Anderson'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'SC'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '29621'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered 'US'	System	13 Apr 2021 13:50:48



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 16:13:43
User entered '2'	System	22 Apr 2021 13:30:27
User entered '1'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:14:46
User entered '22/Apr/2021 09:30'	System	22 Apr 2021 13:30:27

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:58:54

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:14:46
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 13:30:27

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:36
User entered	System	13 Apr 2021 13:50:17
'USA-US100-2021-MRNA-1273-P301000011'		

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Yes (Y)'	System	13 Apr 2021 13:50:17



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'No (N)'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Gowdhami'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Mohan'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '1655 E. Greenville St'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'Anderson'	System	13 Apr 2021 13:50:17

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered 'SC'	System	13 Apr 2021 13:50:17



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 18:20:33
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 13:50:40
User entered '29621'	System	13 Apr 2021 13:50:17

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 16:12:35
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Apr 2021 22:12:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 18:20:33
User entered 'US'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 16:13:43
User entered '2'	System	22 Apr 2021 13:30:27
User entered '1'	System	13 Apr 2021 13:50:48

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000011**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:58:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:40:07
User entered '03/May/2021 12:13'	(b) (4) System	03 May 2021 16:13:43

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000011

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:58:54

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:40:07
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 16:13:43

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered	System	27 Apr 2021 15:27:34
'USA-US100-2021-MRNA-1273-P301000012'		

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Gowdhami'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Mohan'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '1655 E. Greenville St'	System	27 Apr 2021 15:27:34



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Anderson'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'SC'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '29621'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:21:30
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:00:13
User entered 'US'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:21:55
User entered '1'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered	System	27 Apr 2021 15:27:34
'USA-US100-2021-MRNA-1273-P301000012'		

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Gowdhami'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Mohan'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '1655 E. Greenville St'	System	27 Apr 2021 15:27:34



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Anderson'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'SC'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '29621'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:21:30
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:00:13
User entered 'US'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:21:55
User entered '1'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:58:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 18:00:13
User entered '27/Apr/2021 10:28'	System	27 Apr 2021 15:28:11

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:58:54

**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.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:21:30
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:00:13
User entered 'I'	(b) (4), (b) (6)	27 Apr 2021 15:28:11

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered	System	27 Apr 2021 15:27:34
'USA-US100-2021-MRNA-1273-P301000012'		



**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Yes (Y)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'No (N)'	System	27 Apr 2021 15:27:34

US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Gowdhami'	System	27 Apr 2021 15:27:34



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:58:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Mohan'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '1655 E. Greenville St'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'Anderson'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered 'SC'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 18:00:13
Reviewed for Safety.	(b) (4), (b) (6)	27 Apr 2021 15:28:01
User entered '29621'	System	27 Apr 2021 15:27:34

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	29 Apr 2021 19:21:30
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:29
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 18:00:13
User entered 'US'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:58:54**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Apr 2021 19:21:55
User entered '1'	System	27 Apr 2021 15:28:11

**US3832176**

**Folder: SAE USA-US100-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:58:54**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:40:07
User entered '29/Apr/2021 15:21'	(b) (4) System	29 Apr 2021 19:21:55



US3832176

Folder: SAE USA-US100-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:58:54

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	03 May 2021 18:40:07
User entered 'I'	(b) (4)	
	(b) (4), (b) (6)	29 Apr 2021 19:21:55