

US3832211 (Prod: Keystone VitaLink Research - Anderson - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:00:04

All time stamps listed in this document are displayed in GMT

US3832211

**Form: Participant Creation**

**Data signed:** (b) (4) 21 Feb 2021 21:35:20

**Generated On: 10 Jun 2021 10:00:04**

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[Participant ID](#)

US3832211

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

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US3832211

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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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US3832211

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify	
Unknown	False
Not reported	False

US3832211

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Date of Informed Consent (*dd MMM yyyy*) 18 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1

Amendment 2

Amendment 3

Amendment 4

Amendment 5

Was participant enrolled in the study? Yes   
No

If No, indicate reason for screen fail

Withdrew Consent

Inclusion/Exclusion

Cohort Full

Other

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously? Yes   
No

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

US3832211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Did the participant meet all eligibility criteria?

Yes

No

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US3832211

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Were any significant conditions reported?

Yes

No

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US3832211

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	CHRONIC OBSTRUCTIVE PULMONARY DISEASE
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	BENIGN PROSTATIC HYPERPLASIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	DIABETES II
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	CHRONIC PAIN
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	ANGINA PECTORIS
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)	_____

US3832211

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	NEUROPATHY
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)	_____

US3832211

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Condition	OSTEOARTHRITIS BILATERAL EXTREMITIES
Start date (dd MMM yyyy)	UN DEC 2017
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)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3832211

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	18 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:31 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:31
Height ( <i>xxx.x</i> )	184.2 cm
Weight ( <i>xxx.x</i> )	98.9 kg
BMI ( <i>xxx.x</i> )	29.14856 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)	_____

US3832211

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Was the physical examination performed?

Yes

No

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Date of examination (dd MMM yyyy)

18 AUG 2020

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

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US3832211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

**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

**Specify** RETIRED

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

**No Risk Identified** False

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

US3832211

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

<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>	

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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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US3832211

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186568

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

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Height	ND - Not Done
Weight	ND - Not Done

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US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	18 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	15:31 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:31
Temperature ( <i>xxx.x</i> )	97.4 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> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	51 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	18 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	16:51 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:51
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	72 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	95 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	63 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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US3832211

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 16:21 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 16:21

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

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Was the sample collected? Yes  No

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Collection date (*dd MMM yyyy*) 18 AUG 2020

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Collection time (*00:00-23:59*) 16:15 (24 HR)

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Collection date and time (derived) 18 AUG 2020 16:15

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US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Collection date ( <i>dd MMM yyyy</i> )			18 AUG 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:14	18 AUG 2020 16:14
Nasopharyngeal Swab 2	No		

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US3832211

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

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Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**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 97.5 °F

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

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

PC Time Stamp 18 AUG 2020 16:55

PC Open Date & Time 18 AUG 2020 16:41

PC Close Date & Time 18 AUG 2020 19:11

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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 97.5 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 18 AUG 2020 21:24

PC Open Date & Time 18 AUG 2020 20:06

PC Close Date & Time 19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE in °F</b>	98.1 °F
Was any <b>MEDICATION TAKEN today for pain or fever?</b>	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Please confirm reason for pain or fever medication (may select more than one):	
To <b>TREAT</b> pain or fever that has already occurred	False
To <b>PREVENT</b> pain or fever from occurring	True
PC Time Stamp	19 AUG 2020 12:33
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 21 AUG 2020 11:43

PC Open Date & Time 20 AUG 2020 12:00

PC Close Date & Time 21 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 4

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE in °F** 98.3 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 21 AUG 2020 17:17

PC Open Date & Time 21 AUG 2020 12:00

PC Close Date & Time 22 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**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** 98.1 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 22 AUG 2020 19:06

PC Open Date & Time 22 AUG 2020 12:00

PC Close Date & Time 23 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 6

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.2 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 23 AUG 2020 12:45

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes   
No

Please record your **TEMPERATURE** in °F  
Was any **MEDICATION TAKEN** today for pain or fever? Yes   
No

Please confirm reason for pain or fever medication (may select more than one):  
To **TREAT** pain or fever that has already occurred  
To **PREVENT** pain or fever from occurring  
PC Time Stamp  
PC Open Date & Time 24 AUG 2020 12:00  
PC Close Date & Time 25 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 8

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** 98.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 25 AUG 2020 12:01

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 9

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** 98.5 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 27 AUG 2020 11:29

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 10

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** 98.5 °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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 27 AUG 2020 12:01

PC Open Date & Time 27 AUG 2020 12:00

PC Close Date & Time 28 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 11

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):

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 28 AUG 2020 15:39

PC Open Date & Time 28 AUG 2020 12:00

PC Close Date & Time 29 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 12

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 98.5 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 30 AUG 2020 09:12

PC Open Date & Time 29 AUG 2020 12:00

PC Close Date & Time 30 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 13

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 30 AUG 2020 14:43

PC Open Date & Time 30 AUG 2020 12:00

PC Close Date & Time 31 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 14

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 31 AUG 2020 13:05

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 15

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

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

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

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

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

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

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

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

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

PC Time Stamp	02 SEP 2020 10:51
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**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

18 AUG 2020 16:57

PC Open Date & Time

18 AUG 2020 16:41

PC Close Date & Time

18 AUG 2020 19:11

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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

18 AUG 2020 21:27

PC Open Date & Time

18 AUG 2020 20:06

PC Close Date & Time

19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 2

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

19 AUG 2020 12:34

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 3

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

21 AUG 2020 11:43

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**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

21 AUG 2020 17:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 5

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	22 AUG 2020 19:07
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 6

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

23 AUG 2020 12:46

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 7

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity
- Any use of prescription pain reliever or prevents daily activity

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

- Yes
- No

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

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

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

- Yes
- No

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

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

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

Please select one response below

- None
- Does not interfere with activity
- Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity
- Any use of prescription pain reliever or prevents daily activity

PC Time Stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

No   
Yes

---

PC Time stamp	18 AUG 2020 16:56
PC Open Date & Time	18 AUG 2020 16:41
PC Close Date & Time	18 AUG 2020 19:11

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

No   
Yes

PC Time stamp

PC Open Date & Time

18 AUG 2020 20:06

PC Close Date & Time

19 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	19 AUG 2020 12:36
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	21 AUG 2020 11:45
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 10:11
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	22 AUG 2020 19:09
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	23 AUG 2020 12:47
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

Yes

---

PC Time stamp

---

PC Open Date & Time

24 AUG 2020 12:00

---

PC Close Date & Time

25 AUG 2020 11:59

---

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 12:01
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

<b>TIMEPOINT</b>	DAY 9
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 11:30
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 10
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 12:01
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 11
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	28 AUG 2020 15:37
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

<b>TIMEPOINT</b>	DAY 12
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 09:13
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 13
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 14:44
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

<b>TIMEPOINT</b>	DAY 14
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 AUG 2020 13:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

<b>TIMEPOINT</b>	DAY 15
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	02 SEP 2020 10:52
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 8 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

---

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	10:48 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 10:48
Temperature ( <i>xxx.x</i> )	98.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	88 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	15 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	11:42 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 11:42
Temperature ( <i>xxx.x</i> )	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify _____	
Pulse ( <i>xxx</i> )	50 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	56 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

15 SEP 2020

---

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

---

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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) 15 SEP 2020

What was the treatment time? (00:00-23:59) 11:12 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 11:12

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

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 15 SEP 2020

---

Collection time (*00:00-23:59*) 11:06 (24 HR)

---

Collection date and time (derived) 15 SEP 2020 11:06

---

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

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Collection date ( <i>dd MMM yyyy</i> )			15 SEP 2020
Lab Test	Was the sample collected?	Collection time ( <i>00:00 - 23:59</i> )	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:01	15 SEP 2020 11:01
Nasopharyngeal Swab 2	No		

---

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

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

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

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

PC Time Stamp 15 SEP 2020 11:47

PC Open Date & Time 15 SEP 2020 11:32

PC Close Date & Time 15 SEP 2020 14:02

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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 98.3 °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 15 SEP 2020 21:02  
PC Open Date & Time 15 SEP 2020 14:57  
PC Close Date & Time 16 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	16 SEP 2020 14:17
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 3

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day. If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.6 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	17 SEP 2020 12:19
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes  No

Please record your **TEMPERATURE** in °F 98.1 °F

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

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

PC Time Stamp 18 SEP 2020 12:02

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	19 SEP 2020 14:49
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.2 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	20 SEP 2020 15:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	98.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>

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

PC Time Stamp	21 SEP 2020 15:49
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**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

15 SEP 2020 11:48

PC Open Date & Time

15 SEP 2020 11:32

PC Close Date & Time

15 SEP 2020 14:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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

15 SEP 2020 21:02

PC Open Date & Time

15 SEP 2020 14:57

PC Close Date & Time

16 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 2

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	16 SEP 2020 14:18
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 3

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	17 SEP 2020 12:20
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 4

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

18 SEP 2020 12:03

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 5

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

19 SEP 2020 14:49

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 6

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

20 SEP 2020 15:08

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 7

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

21 SEP 2020 15:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

No   
Yes

---

PC Time stamp	15 SEP 2020 11:48
PC Open Date & Time	15 SEP 2020 11:32
PC Close Date & Time	15 SEP 2020 14:02

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

No   
Yes

---

PC Time stamp	15 SEP 2020 21:03
PC Open Date & Time	15 SEP 2020 14:57
PC Close Date & Time	16 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	16 SEP 2020 14:18
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="radio"/>
PC Time stamp	17 SEP 2020 12:21
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 12:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 14:50
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	20 SEP 2020 15:08
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

---

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

---

	Yes <input type="checkbox"/>
PC Time stamp	21 SEP 2020 15:50
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

---

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

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*

---

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:23:51

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 29 SEP 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:23:51

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 06 OCT 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:38

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

---

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	08:28 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:28
Temperature ( <i>xxx.x</i> )	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	_____
Pulse ( <i>xxx</i> )	80 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	65 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	_____
Weight (derived)	_____

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

13 OCT 2020

---

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

---

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 13 OCT 2020

---

Collection time (*00:00-23:59*) 08:46 (24 HR)

---

Collection date and time (derived) 13 OCT 2020 08:46

---

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 14:24:39

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 <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	20 OCT 2020 13:32:52
Patient Cloud Open Date & Time	18 OCT 2020 00:01
Patient Cloud Close Date & Time	22 OCT 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 27 OCT 2020 12:53:15

Patient Cloud Open Date & Time 25 OCT 2020 00:01

Patient Cloud Close Date & Time 29 OCT 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 03 NOV 2020 11:46:37

Patient Cloud Open Date & Time 01 NOV 2020 00:01

Patient Cloud Close Date & Time 05 NOV 2020 23:59

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 NOV 2020 10:42:15
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 96
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	22 NOV 2020 09:31:17
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 30 NOV 2020 09:48:04

Patient Cloud Open Date & Time 26 NOV 2020 00:01

Patient Cloud Close Date & Time 30 NOV 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 DEC 2020 17:03:53
Patient Cloud Open Date & Time	03 DEC 2020 00:01
Patient Cloud Close Date & Time	07 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 DEC 2020 11:43:40
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 DEC 2020 09:53:50
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 DEC 2020 09:53:14
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 31 DEC 2020 05:15:48

Patient Cloud Open Date & Time 31 DEC 2020 00:01

Patient Cloud Close Date & Time 04 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 145

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

No

Yes

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

No

Yes

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

Date and time of submission 09 JAN 2021 22:16:40

Patient Cloud Open Date & Time 07 JAN 2021 00:01

Patient Cloud Close Date & Time 11 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 JAN 2021 21:08:40
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 21 JAN 2021 12:21:55

Patient Cloud Open Date & Time 21 JAN 2021 00:01

Patient Cloud Close Date & Time 25 JAN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	28 JAN 2021 13:21:32
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 04 FEB 2021 11:02:37

Patient Cloud Open Date & Time 04 FEB 2021 00:01

Patient Cloud Close Date & Time 08 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 13 FEB 2021 23:41:46

Patient Cloud Open Date & Time 11 FEB 2021 00:01

Patient Cloud Close Date & Time 15 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 13:26:05
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 FEB 2021 11:28:09
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 08:26:27
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 208

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

No

Yes

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

No

Yes

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

Date and time of submission 11 MAR 2021 14:59:41

Patient Cloud Open Date & Time 11 MAR 2021 00:01

Patient Cloud Close Date & Time 15 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 215

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

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 222

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

No

Yes

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

No

Yes

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

Date and time of submission 25 MAR 2021 13:14:54

Patient Cloud Open Date & Time 25 MAR 2021 00:01

Patient Cloud Close Date & Time 29 MAR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 <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	05 APR 2021 15:16:42
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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 12 APR 2021 15:14:21

Patient Cloud Open Date & Time 08 APR 2021 00:01

Patient Cloud Close Date & Time 12 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 APR 2021 10:00:43
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 APR 2021 10:57:18
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 257

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

No

Yes

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

No

Yes

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

Date and time of submission 29 APR 2021 12:24:17

Patient Cloud Open Date & Time 29 APR 2021 00:01

Patient Cloud Close Date & Time 03 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 MAY 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 MAY 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 MAY 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

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**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

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

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**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 12 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#) 16 AUG 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 SEP 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#) 13 SEP 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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 \_\_\_\_\_

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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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 OCT 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 425

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 14 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 18 OCT 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 21 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#) 25 OCT 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 446

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 467

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 06 DEC 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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16 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#) 30 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#) 03 JAN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3832211**

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

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JAN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

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**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JAN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

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**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	31 JAN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	03 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 FEB 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 APR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 607

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 614

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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  Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 MAY 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 642

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 670

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 JUL 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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   
Yes

Have you been exposed to someone with known SARS-CoV-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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

---

Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2022 23:59

---

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

---

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

---

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59

---

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

Chills \_\_\_\_\_

Cough \_\_\_\_\_

Shortness of breath \_\_\_\_\_

Difficulty breathing \_\_\_\_\_

Fatigue \_\_\_\_\_

Muscle aches \_\_\_\_\_

Body aches \_\_\_\_\_

Headache \_\_\_\_\_

New loss of taste \_\_\_\_\_

New loss of smell \_\_\_\_\_

Sore throat \_\_\_\_\_

Congestion \_\_\_\_\_

Runny nose \_\_\_\_\_

Nausea \_\_\_\_\_

Vomiting \_\_\_\_\_

Diarrhea \_\_\_\_\_

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2022 23:59

---

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2022 23:59

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US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**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°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

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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Please contact your study clinic immediately. Click below to confirm that you have read this 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59

---

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

DAY 796

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

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

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

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

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

- Fever (Temperature  $\geq$  100.4°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

US3832211

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#) 20 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#) 24 OCT 2022 23:59

---

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 10:00:04

---

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 18:35:50

---

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 10 NOV 2020

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 11 JAN 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

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

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

---

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

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) \_\_\_\_\_

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

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.*

---

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 23 MAR 2021

---

Collection time (*00:00-23:59*) 10:17 (24 HR)

---

Collection date and time (derived) 23 MAR 2021 10:17

---

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (dd MMM yyyy) 12 APR 2021

---

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

---

Comments

*If Contact Not Made, please provide Comments*

---

---

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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* \_\_\_\_\_

US3832211

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

---

---

US3832211

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 10:00:04

---

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"/>

---

US3832211

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:00:04

---

Generate Next COVID-19 Assessment

Yes

No

---

US3832211

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

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 19 JAN 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID UNBLND\_DECIDE

---

US3832211

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

Form: Unblinding

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

Date of updated informed consent ( <i>dd MMM yyyy</i> )	19 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> )	19 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

US3832211

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068

---

US3832211

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068
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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:04 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:04
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

Height	72.5 in
Weight	218 lb
BMI (xxx.x)	29.22068
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)	19 JAN 2021
Time of assessment (00:00-23:59)	16:43 (24 HR)
Vital Signs Date and Time (derived)	19 JAN 2021 16:43
Temperature (xxx.x)	98.8 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)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

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

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

19 JAN 2021

---

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

---

US3832211

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

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

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) 19 JAN 2021

What was the treatment time? (00:00-23:59) 16:13 (24 HR)

Treatment Date and Time (derived) 19 JAN 2021 16:13

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

US3832211

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00-23:59*) 15:50 (24 HR)

---

Collection date and time (derived) 19 JAN 2021 15:50

---

US3832211

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 19 JAN 2021

---

Collection time (*00:00 - 23:59*) 15:48

---

Collection Date and Time (derived) 19 JAN 2021 15:48

---

US3832211

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

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 26 JAN 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

---

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

---

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 17 FEB 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD29

---

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	17 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	09:40 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 09:40
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> )	79 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	66 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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 ( <i>dd MMM yyyy</i> )	17 FEB 2021
Time of assessment ( <i>00:00-23:59</i> )	10:18 (24 HR)
Vital Signs Date and Time (derived)	17 FEB 2021 10:18
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> )	81 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	70 mmHg
Diastolic Blood Pressure units	MMHG

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

Was the physical examination performed?

Yes

No

---

Date of examination (dd MMM yyyy)

17 FEB 2021

---

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

---

US3832211

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

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) 17 FEB 2021

What was the treatment time? (00:00-23:59) 09:46 (24 HR)

Treatment Date and Time (derived) 17 FEB 2021 09:46

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

US3832211

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 12:11:39

Generated On: 10 Jun 2021 10:00:04

---

Was Contact Attempted? Yes   
No

---

Date of Contact or Contact Attempt (*dd MMM yyyy*) 24 FEB 2021

---

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

---

Comments

---

*If Contact Not Made, please provide Comments*

---

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 12:11:39

Generated On: 10 Jun 2021 10:00:04

---

Is the participant continuing to the next visit?

Yes

No

---

Continuing Flag

1

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Was this visit performed? Yes   
No

---

Visit date (dd MMM yyyy) 23 MAR 2021

---

Was visit performed at the participant's home or at the clinic? Home   
Clinic

---

Folder OID OLD57

---

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

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) \_\_\_\_\_

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

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.*

---

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 23:15:53

Generated On: 10 Jun 2021 10:00:04

---

Was the sample collected? Yes  No

---

Collection date (*dd MMM yyyy*) 23 MAR 2021

---

Collection time (*00:00-23:59*) 10:17 (24 HR)

---

Collection date and time (derived) 23 MAR 2021 10:17

---

US3832211

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

Did the participant experience any adverse events?

Yes

No

---

If Yes, enter details on the Adverse Events form.

---

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

AEID USA-US100-2020-MRNA-1273-P30  
1000006

Adverse event COPD EXACERBATION

Was this a medically-attended AE? Yes   
No

Was this a Solicited Adverse Reaction? Yes   
No

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes   
No

Start date (dd MMM yyyy) 8 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes   
No

If not Ongoing, end date (dd MMM yyyy) 16 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild   
Grade 2/Moderate   
Grade 3/Severe   
Grade 4

Is the adverse event serious? Yes   
No

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization True

Hospital Admission Date (dd MMM yyyy) 8 OCT 2020

Hospital Discharge Date (dd MMM yyyy) 9 OCT 2020

Admitted to ICU? Yes   
No   
Unknown

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2662

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

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   
Related   
Not Applicable

---

Relationship to Study Procedure Not Related   
Related   
Not Applicable

---

Action taken with investigational product None   
Dose Delayed   
Investigational Product   
Withdrawn   
Not Applicable

---

Other action taken (check all that apply)

---

None False

---

Concomitant Medication True

---

Concomitant Procedure False

---

Outcome Fatal   
Not Recovered/Not Resolved   
Recovered/Resolved   
Recovered/Resolved with   
Sequelae   
Recovering/Resolving   
Unknown

---

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: \_\_\_\_\_

Narrative

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

76 Y/O RANDOMIZED MALE WHO RECEIVED THE FIRST DOSE OF BLINDED MRNA-1273 OR PLACEBO FOR SARS-COV-2 VACCINATION ON 8/18/2020 AND HIS SECOND, FINAL DOSE OF STUDY DRUG, ON 09/15/2020. PRESENTED TO THE ER ON 10/8/2020 WITH WORSENING OF SHORTNESS OF BREATH PER ER RECORDS SPO2 WAS AT 75% PRIOR TO O2 ADMINISTRATION UPON ADMISSION SPO2 WAS AT 94%. SUBJECT STATES HE WAS SEEN BY HIS PULMONOLOGIST 10/7/2020 AND WAS DIAGNOSED WITH A COPD EXACERBATION THE SUBJECT WAS TREATED WITH , PREDNISONE, AND O2 AT 4L. SUBJECT WAS ADMITTED AND TREATED WITH BENZONATATE 200MG TID PRN X7 DAYS, DOXYCYCLINE 100MG 1 PO BID X 7 DAYS, GUAIFENESIN 600MG BID X 7 DAYS IPRATROPIUM-ALBUTEROL 20-100MCG 1 PUFF QID, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. COVID TESTING AS WELL AS INFLUENZA A AND B TESTING COMPLETED BOTH WITH NEGATIVE RESULTS. CHEST XRAY COMPLETED RESULTS WITHIN NORMAL LIMITS.

---

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)	

---

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

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

Yes

No

---

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

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ALBUTEROL SULFATE HFA

Prophylaxis Yes   
No

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 90

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

374 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) UN JUN 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) \_\_\_\_\_

Interval Dosage Unit Number (derived) \_\_\_\_\_

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication CARVEDILOL

Prophylaxis Yes   
No

Indication HYPERTENSION

Dose per administration 3.125

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)

376 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication VITAMIN D3

Prophylaxis Yes   
No

Indication SUPPLEMENT

Dose per administration 5000

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)

378 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication DUONEB

Prophylaxis Yes   
No

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 3

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

380 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Ongoing?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

---

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input type="checkbox"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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)

382 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication FINASTERIDE

Prophylaxis Yes   
No

Indication BENIGN PROSTATIC  
HYPERPLASION

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

384 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="radio"/>
	803 <input type="radio"/>
	804 <input checked="" type="radio"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication GABAPENTIN

Prophylaxis Yes   
No

Indication NEUROPATHY

Dose per administration 800

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)

386 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 3

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication HUMALOG

Prophylaxis Yes   
No

Indication DIABETES TYPE II

Dose per administration 100

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify UNITS/ML

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

388 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication HYDROCODONE-ACETAMINOP  
HEN

Prophylaxis Yes   
No

Indication CHRONIC PAIN

Dose per administration 10/325

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

390 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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 JAN 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 2

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication LEVOTHYROXINE

Prophylaxis Yes   
No

Indication HYPOTHYROIDISM

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

392 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

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 2016

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication MONTELUKAST

Prophylaxis Yes   
No

Indication ALLERGIC RHINITIS

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

394 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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 MAY 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication NITROGLYCERIN

Prophylaxis Yes   
No

Indication ANGINA

Dose per administration .4

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

396 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
<i>If route of administration is Other, specify</i>	SUBLINGUAL	
<i>Start date (dd MMM yyyy)</i>	UN UNK 2010	
<i>Start date completely unknown</i>	False	
<i>Ongoing?</i>	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<i>If not Ongoing, End date (dd MMM yyyy)</i>		
<i>Was this medication taken for solicited event?</i>	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<i>Separate Dosage Number (derived)</i>		
<i>Interval Dosage Unit Number (derived)</i>		
<i>Interval Dosage Definition (derived)</i>	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ROPINIROLE

Prophylaxis Yes   
No

Indication RESTLESS LEG SYNDROME

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

398 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication SETRALINE

Prophylaxis Yes   
No

Indication DEPRESSION

Dose per administration 50

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)

400 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication SYMBICORT

Prophylaxis Yes   
No

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE

Dose per administration 160/4.5

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

402 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date (dd MMM yyyy)	UN UNK 2014
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"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication TAMSULOSIN

Prophylaxis Yes   
No

Indication BENIGN PROSTATIC  
HYPERPLASIA

Dose per administration .4

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

404 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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 2016
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"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication TRAZODONE

Prophylaxis Yes   
No

Indication INSOMNIA

Dose per administration 50

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)

406 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

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   
No

---

If not Ongoing, End date (*dd MMM yyyy*) \_\_\_\_\_

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) \_\_\_\_\_

---

Interval Dosage Unit Number (derived) \_\_\_\_\_

---

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication ATORVASTATIN

Prophylaxis Yes   
No

Indication HYPERLIPIDEMIA

Dose per administration 80

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

408 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
<hr/>		
If route of administration is Other, specify	<hr/>	
Start date ( <i>dd MMM yyyy</i> )	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
<hr/>		
If not Ongoing, End date ( <i>dd MMM yyyy</i> )	<hr/>	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
<hr/>		
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"/>

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication MELOXICAM

Prophylaxis Yes   
No

Indication OSTEOARTHRITIS BILATERAL  
EXTREMITIES

Dose per administration 15

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

410 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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 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"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication BENZONATATE

Prophylaxis Yes   
No

Indication ADVERSE EVENT - CHRONIC  
OBSTRUCTIVE PULMONARY  
DISEASE EXACERBATION

Dose per administration 200

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

412 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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)	9 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication DOXYCYCLINE

Prophylaxis Yes   
No

Indication ADVERSE EVENT - CHRONIC  
OBSTRUCTIVE PULMONARY  
DISEASE EXACERBATION

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

414 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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)	9 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication GUAIFENESIN

Prophylaxis Yes   
No

Indication CHRONIC OBSTRUCTIVE  
PULMONARY DISEASE  
EXACERBATION

Dose per administration 600

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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)	9 OCT 2020
--------------------------	------------

---

Start date completely unknown	False
-------------------------------	-------

---

Ongoing?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

If not Ongoing, End date (dd MMM yyyy)	16 OCT 2020
--	-------------

---

Was this medication taken for solicited event?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	2
----------------------------------	---

---

Interval Dosage Unit Number (derived)	1
---------------------------------------	---

---

Interval Dosage Definition (derived)	802 <input type="checkbox"/>
	803 <input type="checkbox"/>
	804 <input checked="" type="checkbox"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication COMBIVENT RESPIMAT  
(IPRATROPIUM ALBUTEROL)

Prophylaxis Yes   
No

Indication ADVERSE EVENT - CHRONIC  
OBSTRUCTIVE PULMONARY  
DISEASE EXACERBATION

Dose per administration 1

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify \_\_\_\_\_

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

If frequency is Other, specify \_\_\_\_\_

Route of administration Oral   
Topical   
Subcutaneous

PRODUCTION RELEASE (v12.003  
EAB) (1725)

418 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal
- Rectal
- Intravenous
- Intravenous Bolus
- Intravenous Drip
- Other

If route of administration is Other, specify \_\_\_\_\_

Start date (dd MMM yyyy) 9 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) \_\_\_\_\_

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 4

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes   
No

Indication COPD EXACERBATION

Dose per administration 40

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

420 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

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*) 08 OCT 2020

---

Start date completely unknown False

---

Ongoing? Yes   
No

---

If not Ongoing, End date (*dd MMM yyyy*) 10 OCT 2020

---

Was this medication taken for solicited event? Yes   
No

---

Separate Dosage Number (derived) 1

---

Interval Dosage Unit Number (derived) 1

---

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes   
No

Indication COPD EXACERBATION

Dose per administration 20

Dose unit mg   
ug   
mL   
g   
IU   
tablet   
capsule   
puff   
Other

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral   
Topical   
Subcutaneous   
Transdermal   
Intraocular

PRODUCTION RELEASE (v12.003  
EAB) (1725)

422 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	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 ( <i>dd MMM yyyy</i> )	11 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date ( <i>dd MMM yyyy</i> )	13 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication PREDNISONE

Prophylaxis Yes   
No

Indication COPD EXACERBATION

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

424 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

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) 14 OCT 2020

Start date completely unknown False

Ongoing? Yes   
No

If not Ongoing, End date (dd MMM yyyy) 14 OCT 2020

Was this medication taken for solicited event? Yes   
No

Separate Dosage Number (derived) 1

Interval Dosage Unit Number (derived) 1

Interval Dosage Definition (derived) 802   
803   
804

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

Name of Medication OXYGEN

Prophylaxis Yes   
No

Indication COPD EXACERBATION

Dose per administration 0.004

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)

426 of 2662

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 29 Apr 2021 02:21:33

Generated On: 10 Jun 2021 10:00:04

---

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>

---

If route of administration is Other, specify \_\_\_\_\_

---

Start date ( <i>dd MMM yyyy</i> )	08 OCT 2020
Start date completely unknown	False
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
If not Ongoing, End date ( <i>dd MMM yyyy</i> )	08 OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

---

Separate Dosage Number (derived)	_____
Interval Dosage Unit Number (derived)	_____
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input type="checkbox"/>

---

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

---

Were any concomitant procedures performed?

Yes

No

---

If yes, please complete Concomitant Procedures form.

---

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 21 Feb 2021 21:35:20

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 OCT 2020	CHEST X-RAY(WNL)	Adverse Event	
08 OCT 2020	COVID 19 TEST (NEGATIVE)	Adverse Event	
08 OCT 2020	INFLUENZA A AND B TESTING (NEGATIVE)	Adverse Event	

US3832211

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:00:04

---

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

---

US3832211

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:00:04

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

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P30 1000006
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

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
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)	14/OCT/2020 09:41
<b>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.</b>	<input checked="" type="checkbox"/> True

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
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/NOV/2020 14:29
<b>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.</b>	<input checked="" type="checkbox"/> True

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 21 Feb 2021 21:35:31

Generated On: 10 Jun 2021 10:00:04

SAEID	USA-US100-2020-MRNA-1273-P301000006
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)	10/FEB/2021 10:50
<b>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.</b>	True

Audit

US3832211 (Prod: Keystone VitaLink Research - Anderson - PPDS)

US3832211

Form: Participant Creation

Generated On: 10 Jun 2021 10:00:04

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'US3832211'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:15

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:16

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:34:55
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'SCRN'	System	18 Aug 2020 19:10:24

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:17

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '76'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'YEARS'	System	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '76'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered 'Male (M)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:00:04

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:31
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:33

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Aug 2020'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Amendment 2 (2)'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:10:48

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:09:16

US3832211

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:00:04

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '1'	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:35:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 10:00:04

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:36:09
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:10:57

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: Chronic obstructive pulmonary disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
Data point term sent to Coder	System	18 Aug 2020 19:12:22
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:51
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2005'	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2005'	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:32

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:27
Data point term sent to Coder	System	18 Aug 2020 19:12:24
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:12:16
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:11:42

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
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) (b) (4)	18 Aug 2020 23:26:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:28
Data point term sent to Coder	System	18 Aug 2020 19:12:24
User entered 'Atrial Fibrillation'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:13:55
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:12

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User coded data point as SOC: Reproductive system and breast disorders, HLG: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: Benign prostatic hyperplasia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Benign prostatic hyperplasia'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:14:45
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2010'	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2010'	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:31

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Diabetes II'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered 'un UNK 2004'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:15:44
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2004'	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2004'	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:42

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
Query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:44:49
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 01:37:00
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:32:52
User opened query 'Per DM CLR: Please specify the location and/or type of CHRONIC PAIN. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 08:43:28
User coded data point as SOC: General disorders and administration site conditions, HLT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:27
User entered 'Chronic Pain'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:22
User entered 'un UNK 2005'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:24
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:27
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:30
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2005'	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2005'	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:12:53

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2014'	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2014'	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:03

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:30
Data point term sent to Coder	System	18 Aug 2020 19:13:30
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2020'	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:17

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Angina pectoris - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:12:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 14:12:41
Data point term sent to Coder	System	23 Sep 2020 14:10:43
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	System	23 Sep 2020 14:10:13
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' answered with 'Updated' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:10:13
Coding entries removed.	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:10:07
User entered 'Angina Pectoris' reason for change:	Danyel Johnson (b) (4)	23 Sep 2020 14:10:07
Data Entry Error	(b) (4)	
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc). ' (Site from System).	Coder Import (b) (4) (b) (4)	24 Aug 2020 19:34:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:29

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0. Data point term sent to Coder	Coder Import (b) (4) (b) (4) System	18 Aug 2020 23:26:29 18 Aug 2020 19:13:30
User entered 'Chest pain'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2000'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2000'	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2000'	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:28

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:34
User entered 'Restless leg syndrome'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2017'	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2017'	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:13:53

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Psychiatric disorders, HLT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:34
Data point term sent to Coder	System	18 Aug 2020 19:14:32
User entered 'Depression'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2020'	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2020'	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:03

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
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)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:34
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2006'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2006'	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2006'	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:11

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:26:32
Data point term sent to Coder	System	18 Aug 2020 19:14:36
User entered 'Sleep apnea'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'un UNK 2006'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:32:52
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2006'	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2006'	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	18 Aug 2020 19:14:24

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 06:29:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 06:29:41
Data point term sent to Coder	System	02 Nov 2020 18:00:23
User entered 'Neuropathy'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'UN UNK 2011'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2011'	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2011'	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	02 Nov 2020 18:00:04

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Metabolism and nutrition disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 20:51:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Dec 2020 20:51:42
Data point term sent to Coder	System	14 Dec 2020 20:51:02
User entered 'HYPERLIPIDEMIA'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'un UNK 2012'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Jan 2012'	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2012'	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (15)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 20:50:48

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 21:12:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 21:12:52
Data point term sent to Coder	System	14 Dec 2020 21:12:25
User entered 'OSTEOARTHRITIS Bilateral extremities'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'un Dec 2017'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	Danyel Johnson (b) (4)	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'Dec 2017'	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '2017'	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Medical History (16)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered empty.	System	14 Dec 2020 21:12:19

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '15:31'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered '18 Aug 2020 15:31'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '184.2' cm	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46
DataPoint set to visible.	(b) (4) System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '98.9' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46
DataPoint set to visible.	(b) (4) System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
Amendment Manager: User entered '29.14856'	System	17 Sep 2020 00:12:44
User entered '29.1'	System	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'kg/m2'	System	18 Aug 2020 19:44:46
DataPoint set to visible.	System	18 Aug 2020 19:10:52

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:43
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:25
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:25
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:43
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:20
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:16
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:10
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:28:52
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '97.4' F	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:12:33
Query 'please delete' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 16:03:24
User entered empty; reason for change Data Entry Error	(b) (4)	05 Nov 2020 16:03:01
User opened query 'please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:28:54
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46
	(b) (4)	

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 00:29:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:46
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:41
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:41
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:45
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:32
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:28
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:31
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:16
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '70'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'bpm'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'bpm'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:49
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:39
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:49
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:47
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:42
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:36
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:37
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:17
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '14'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'breaths/min'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'breaths/min'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:52
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:42
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:56
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:12:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:49
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:50
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:46
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:44
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:21
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04
User entered '102'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'mmHg'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'mmHg'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:50:56
Query 'per query response, ND. Please enter "ND" directly into the database.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:44:45
User entered missing code ND - Not Done; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 21:43:36
User opened query 'per query response, ND. Please enter "ND" directly into the database.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:13:06
User closed query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 20:13:06
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 19:35:51
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:59
Query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' answered with 'ND' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:54
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Nov 2020 16:03:01
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 16:03:01
User opened query 'Per EDC guidelines, ND must be entered if Day 0 and Day 1 are performed same date, then this is only entered on Day 1. Please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:29:51
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:29:20
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:04

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
User closed query 'Diastolic Blood Pressure reported is out of range &lt; 60 or &gt; 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:47:14
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS per Sub-I' (Site from System).	Danyel Johnson (b) (4)	23 Sep 2020 14:10:49
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '51'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User entered 'mmHg'	System	10 Nov 2020 21:43:36
User entered empty.	System	05 Nov 2020 16:03:01
User entered 'mmHg'	System	18 Aug 2020 19:44:46

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53

US3832211

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53

US3832211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:14
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:14

US3832211

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:14
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	24 Sep 2020 15:59:38
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		15 Sep 2020 14:35:23
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:11:14

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

**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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

**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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

**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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered 'retired' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '0'	(b) (4) Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4) Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User entered '1' reason for change: Data Entry Error	(b) (4) Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:27
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:14:54

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Please delete' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:16:25
Query 'Please delete' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:10
User entered '0' reason for change: Data Entry Error	(b) (4) Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User opened query 'Please delete' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:39:57
User entered '1'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 19:14:54
	(b) (4)	

US3832211

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:00:04

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:22:53
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 20:16:27
Query 'This section is for living conditions, please verify and reconcile.' answered with 'updated ' (Site from CRA).	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:16
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 18:31:02
User opened query 'This section is for living conditions, please verify and reconcile.' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:40:16
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 00:39:59
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:39:27
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)	18 Aug 2020 19:14:54

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:39:41
User entered 'Clinic (Clinic)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT1'	System	18 Aug 2020 19:44:58

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:23:50
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:23:50
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 19:49:33
User entered '186568' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:49:33

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:41:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 19:45:18

US3832211

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:00:04

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 15:32:21
User closed query 'please enter data' (Site from CRA).	(b) (4), (b) (6)	01 Dec 2020 15:32:19
Query 'please enter data' answered with 'Updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	28 Nov 2020 23:40:26
User entered 'No (N)'	Danyel Johnson (b) (4) (b) (4)	28 Nov 2020 23:40:19
User opened query 'please enter data' (Site from CRA).	(b) (4), (b) (6)	25 Nov 2020 20:16:28
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:22:38

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '15:31'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 15:31'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '97.4' F	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '70'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '14'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User entered '102'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:24
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 07:48:18
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS per Sub-I' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:11:16
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '51'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:13:55
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' answered with 'CORRECTED' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:43
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:17:35
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 10:09:49
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:42:51
User entered '184.2' cm	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Danyel Johnson (b) (4)	14 Dec 2020 21:17:35
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	14 Dec 2020 21:17:35
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 00:26:50
Query 'Per source, weight shows inaccurate. Please review and reconcile.' canceled (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 00:26:47
User opened query 'Per source, weight shows inaccurate. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 01:42:44
User entered '98.8' kg	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 21:06:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 21:06:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:53:52
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '18 Aug 2020' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	18 Aug 2020 21:06:07
User entered '16:51' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:51'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '97.5' F reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered 'Oral (Oral)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '72' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '15' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '95' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:45
User entered '63' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 21:06:07
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	18 Aug 2020 21:06:07
User entered empty.	System	18 Aug 2020 20:53:52

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:56
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:54:31

US3832211

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:43:56
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:54:31

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered '16:21'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:21'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'Left Arm (LEFT ARM)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:13
User entered 'ONCE'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 20:26:12

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 06:27:39
Query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.' answered with 'Immuno samples collected are for Day 1 visit 1 collected 8/18/2020' (Site from DM).	Danyel Johnson (b) (4)	14 Dec 2020 21:17:11
User opened query 'Per GCL Lab recon (LB4 - IMMUNO 5) - Sample dated 18 AUG 2020 is reported under Visit 1 Day 1 in EDC, however the same IMMUNO 5 Sample is reported under Unscheduled [1] visit in PPD Central lab (Immuno 5 records). Please confirm the correct Visit in the response and update if applicable in EDC or PPD Portal. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 13:04:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 09:02:09
Query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' answered with 'Per PPD the samples have been received ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	05 Nov 2020 20:46:24
User opened query 'Per GCL Lab recon: Immunogenicity- Sample collection date for Visit1 Day 1 is recorded as 18-AUG-2020. However, collection date is missing in GCL. Please confirm if 18-AUG-2020 is correct date to update in GCL records.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 08:09:28
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:44:24
User entered '16:15'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:15'	System	18 Aug 2020 20:55:32

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '18 Aug 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '16:14'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '18 Aug 2020 16:14'	System	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4) Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:56:36
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 20:56:36
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:36
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:56:04
User entered empty.	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Un-verified.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:19
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 01:45:12
User entered '16:14' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:36
User entered empty.	(b) (4)	
	Alyssa-Kay Peay (b) (4)	18 Aug 2020 20:56:04
	(b) (4)	

US3832211

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered empty.	System	11 Nov 2020 19:06:19
User entered '18 Aug 2020 16:14'	System	18 Aug 2020 20:56:36
User entered empty.	System	18 Aug 2020 20:56:04

US3832211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:45:16
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	18 Aug 2020 20:56:41

US3832211

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '1'	System	18 Aug 2020 20:56:41

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:54:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered 'Yes (Y)'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered '97.5'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered 'No (N)'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '84e53926-feb3-47f2-83e4-c775eb33129d'	System	18 Aug 2020 20:55:46
User entered '18 Aug 2020 16:55'	System	18 Aug 2020 20:55:46

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:22:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered 'Yes (Y)'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:23:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '97.5'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:23:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered 'Yes (Y)'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '0'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding.' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:09
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:30:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '1'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:24:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8582f02d-9e32-4857-99d9-ea1cf7023dbf'	System	19 Aug 2020 01:24:59
User entered '18 Aug 2020 21:24'	System	19 Aug 2020 01:24:59

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:30:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered 'Yes (Y)'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:31:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '98.1'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:31:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered 'Yes (Y)'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:32:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '0'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:13
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:32:59
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:32:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef'	System	19 Aug 2020 16:33:04
User entered '1'	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ddaef43-f494-482d-994d-cbb1f3c747ef' User entered '19 Aug 2020 12:33'	System	19 Aug 2020 16:33:04
	System	19 Aug 2020 16:33:04

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:41:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered 'Yes (Y)'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '98.0'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered 'Yes (Y)'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:21
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:33:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '1'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:23
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:42:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '1'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '101c7eed-7d65-4771-a1ed-734ca9915f60'	System	21 Aug 2020 15:43:07
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 15:43:07

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:16:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered 'Yes (Y)'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '98.3'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered 'Yes (Y)'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '0'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:27
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '1'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:17:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0558c363-12cc-4af1-8105-97ccc1df4ef5'	System	21 Aug 2020 21:17:52
User entered '21 Aug 2020 17:17'	System	21 Aug 2020 21:17:52

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered 'Yes (Y)'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:05:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '98.1'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:05:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered 'Yes (Y)'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '0'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:31
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:33:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '1'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2474873b-f5d7-46af-be03-0de700e4bcc1'	System	22 Aug 2020 23:06:29
User entered '22 Aug 2020 19:06'	System	22 Aug 2020 23:06:29

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered 'Yes (Y)'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '98.2'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered 'Yes (Y)'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '0'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:33
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4)	31 Aug 2020 20:33:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:44:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '1'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '01399c2e-80bc-4910-b9fe-e8b3a535de10'	System	23 Aug 2020 16:45:13
User entered '23 Aug 2020 12:45'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	23 Aug 2020 16:45:13
User entered 'Day 8'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:00:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered 'Yes (Y)'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '98.5'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered 'Yes (Y)'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:38
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:34:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '1'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '0'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f3cc03f7-ca34-4add-b5d6-00b42bd3b286'	System	25 Aug 2020 16:01:58
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 9'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered 'Yes (Y)'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '98.5'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:28:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered 'Yes (Y)'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '0'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:42
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:34:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '1'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:29:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '10c67fdb-1cc1-41b2-9855-cac93fa3ead6'	System	27 Aug 2020 15:29:48
User entered '27 Aug 2020 11:29'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 10'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:00:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered 'Yes (Y)'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '98.5'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered 'Yes (Y)'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '0'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:45
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '1'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe7272b-e746-4886-808f-e17caa1f9eee'	System	27 Aug 2020 16:01:53
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 15:29:48
User entered 'Day 11'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:02', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered 'Yes (Y)'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '98.2'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:38:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered 'Yes (Y)'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '0'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:49
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '1'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:39:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7ab6c019-fd90-4eaf-a7e0-57ee456ab003'	System	28 Aug 2020 19:39:30
User entered '28 Aug 2020 15:39'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 16:01:53
User entered 'Day 12'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:11:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered 'Yes (Y)'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '98.5'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered 'Yes (Y)'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '1'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '0'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:12:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c92538ac-1313-4175-a2fe-d0cb809ed04b'	System	30 Aug 2020 13:24:30
User entered '30 Aug 2020 09:12'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	28 Aug 2020 19:39:30
User entered 'Day 13'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered 'Yes (Y)'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '98.6'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered 'Yes (Y)'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '0'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:54
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '1'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:43:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dd89d3cc-63b0-4ee0-9dff-51156d3d8d63'	System	30 Aug 2020 18:43:54
User entered '30 Aug 2020 14:43'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 13:24:30
User entered 'Day 14'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered 'Yes (Y)'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '98.6'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered 'Yes (Y)'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:58
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '1'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject reports that he takes medication for chronic pain. He did not have pain or fever related to the vaccine. Subject reeducated on proper completion of diary and verbalized understanding' (Site from System).	(b) (4), (b) (6)	02 Sep 2020 17:52:59
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	31 Aug 2020 20:35:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '1'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:05:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9ba2e6ac-ecb3-4c58-a11e-dc1f96254e16'	System	31 Aug 2020 17:16:17
User entered '31 Aug 2020 13:05'	System	31 Aug 2020 17:16:17

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 18:43:54
User entered 'Day 15'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered 'Yes (Y)'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered '98.3'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered 'No (N)'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:51:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f44fb18a-fb18-4f91-8b9e-47587da5dc4e'	System	02 Sep 2020 14:51:54
User entered '02 Sep 2020 10:51'	System	02 Sep 2020 14:51:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'None (1)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'No (N)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'No (N)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered 'None (1)'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:57:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '2b3efade-8b02-479c-a223-1fa17295f7bd'	System	18 Aug 2020 20:57:47
User entered '18 Aug 2020 16:57'	System	18 Aug 2020 20:57:47

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'None (1)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'No (N)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:25:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'No (N)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:26:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered 'None (1)'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T21:27:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0aad29c-6c70-4047-8397-39047c0fa3d5'	System	19 Aug 2020 01:27:07
User entered '18 Aug 2020 21:27'	System	19 Aug 2020 01:27:07

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'None (1)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'No (N)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'No (N)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:33:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered 'None (1)'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:34:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '16ac29a4-a1c4-4be6-8593-6f1bad71299d'	System	19 Aug 2020 16:34:19
User entered '19 Aug 2020 12:34'	System	19 Aug 2020 16:34:19

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'None (1)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'No (N)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'No (N)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered 'None (1)'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:43:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9fb0268e-ed45-4d1b-a676-72804337b752'	System	21 Aug 2020 15:43:59
User entered '21 Aug 2020 11:43'	System	21 Aug 2020 15:43:59

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'None (1)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'No (N)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'No (N)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f'	System	21 Aug 2020 21:18:52
User entered 'None (1)'	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T17:18:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a666dcf-1d8c-4e4e-a853-fee0bc1b772f' User entered '21 Aug 2020 17:18'	System	21 Aug 2020 21:18:52
	System	21 Aug 2020 21:18:52

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:06:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'None (1)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'No (N)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'No (N)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered 'None (1)'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:07:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab442c07-659c-4061-afc4-bef6569803ca'	System	22 Aug 2020 23:07:32
User entered '22 Aug 2020 19:07'	System	22 Aug 2020 23:07:32

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'None (1)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'No (N)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:45:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'No (N)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered 'None (1)'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '47075793-93ab-4617-ae1e-153849e624f6'	System	23 Aug 2020 16:46:13
User entered '23 Aug 2020 12:46'	System	23 Aug 2020 16:46:13

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:55:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'None (0)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered 'No (N)'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-18T16:56:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7a13799e-b810-4587-9e38-ffba8d25a490'	System	18 Aug 2020 20:56:43
User entered '18 Aug 2020 16:56'	System	18 Aug 2020 20:56:43

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 16:41'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 19:11'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Aug 2020 20:06'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 2'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:34:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:35:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f'	System	19 Aug 2020 16:36:39
User entered 'None (0)'	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f' User entered 'No (N)'	System	19 Aug 2020 16:36:39
	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-19T12:36:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '09ba5e09-da91-4a8a-b158-2f7e6103529f' User entered '19 Aug 2020 12:36'	System	19 Aug 2020 16:36:39
	System	19 Aug 2020 16:36:39

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 3'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:44:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:06', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'None (0)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered 'No (N)'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-21T11:45:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ddd82fa8-3a2f-4fc5-b10f-795ede23c88b'	System	21 Aug 2020 15:45:35
User entered '21 Aug 2020 11:45'	System	21 Aug 2020 15:45:35

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 4'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:09:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:10:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:10:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'None (0)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:11:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered 'No (N)'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T10:11:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1f056158-a6d6-47a9-bf89-d0cd4fd58530'	System	22 Aug 2020 14:11:21
User entered '22 Aug 2020 10:11'	System	22 Aug 2020 14:11:21

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 5'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:08:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:08:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'None (0)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered 'No (N)'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-22T19:09:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b075c669-3213-478e-9648-4dfdc9d98e30'	System	22 Aug 2020 23:09:51
User entered '22 Aug 2020 19:09'	System	22 Aug 2020 23:09:51

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 6'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:46:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'None (0)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered 'No (N)'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-23T12:47:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '02f85072-68f6-4856-af6f-a972e4d112cf' User entered '23 Aug 2020 12:47'	System	23 Aug 2020 16:47:22
	System	23 Aug 2020 16:47:22

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 7'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	23 Aug 2020 16:45:13
User entered 'Day 8'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5fd7ede2-a63d-4566-a9a0-85795229019a'	System	25 Aug 2020 16:02:29
User entered 'No (N)'	System	25 Aug 2020 16:02:29

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5fd7ede2-a63d-4566-a9a0-85795229019a' User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:02:29
	System	25 Aug 2020 16:02:29

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 16:45:13

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 9'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:30:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '81114c94-5128-4365-96bb-f20cf8f8b38e'	System	27 Aug 2020 15:30:30
User entered 'No (N)'	System	27 Aug 2020 15:30:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T11:30:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '81114c94-5128-4365-96bb-f20cf8f8b38e'	System	27 Aug 2020 15:30:30
User entered '27 Aug 2020 11:30'	System	27 Aug 2020 15:30:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(9)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	25 Aug 2020 16:01:58
User entered 'Day 10'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8b4e877f-b5a3-42da-86c5-bf75c4132b5d'	System	27 Aug 2020 16:02:26
User entered 'No (N)'	System	27 Aug 2020 16:02:26

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-27T12:01:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8b4e877f-b5a3-42da-86c5-bf75c4132b5d'	System	27 Aug 2020 16:02:26
User entered '27 Aug 2020 12:01'	System	27 Aug 2020 16:02:26

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(10)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 16:01:58

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 15:29:48
User entered 'Day 11'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:37:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8c92d6dc-5a30-4848-85fe-12d8046dfa14'	System	28 Aug 2020 19:37:48
User entered 'No (N)'	System	28 Aug 2020 19:37:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-28T15:37:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '8c92d6dc-5a30-4848-85fe-12d8046dfa14'	System	28 Aug 2020 19:37:48
User entered '28 Aug 2020 15:37'	System	28 Aug 2020 19:37:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(11)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 15:29:48

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	27 Aug 2020 16:01:53
User entered 'Day 12'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:13:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '08362b3b-8643-4932-a47a-0000e983267f'	System	30 Aug 2020 13:14:40
User entered 'No (N)'	System	30 Aug 2020 13:14:40

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T09:13:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '08362b3b-8643-4932-a47a-0000e983267f'	System	30 Aug 2020 13:14:40
User entered '30 Aug 2020 09:13'	System	30 Aug 2020 13:14:40

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(12)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 16:01:53

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	28 Aug 2020 19:39:30
User entered 'Day 13'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:44:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '43958f30-ba73-45cb-8b8f-c9dd66d716f0'	System	30 Aug 2020 18:44:30
User entered 'No (N)'	System	30 Aug 2020 18:44:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-30T14:44:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '43958f30-ba73-45cb-8b8f-c9dd66d716f0'	System	30 Aug 2020 18:44:30
User entered '30 Aug 2020 14:44'	System	30 Aug 2020 18:44:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(13)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:39:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 13:24:30
User entered 'Day 14'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:04:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '22c88ef8-6fe0-4443-a041-71406be9a043'	System	31 Aug 2020 17:15:52
User entered 'No (N)'	System	31 Aug 2020 17:15:52

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-08-31T13:04:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '22c88ef8-6fe0-4443-a041-71406be9a043'	System	31 Aug 2020 17:15:52
User entered '31 Aug 2020 13:04'	System	31 Aug 2020 17:15:52

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(14)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 13:24:30

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	30 Aug 2020 18:43:54
User entered 'Day 15'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:52:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '860ba4a0-efbc-4ca7-91ce-156281115b62'	System	02 Sep 2020 14:52:16
User entered 'No (N)'	System	02 Sep 2020 14:52:16

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-02T10:52:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '860ba4a0-efbc-4ca7-91ce-156281115b62'	System	02 Sep 2020 14:52:16
User entered '02 Sep 2020 10:52'	System	02 Sep 2020 14:52:16

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:43:54

US3832211

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(15)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:43:54

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered 'Yes (Y)'	Emma Partin (b) (4) (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered '25 Aug 2020'	Emma Partin (b) (4) (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered 'Contact Made (CONTACT MADE)'	Emma Partin (b) (4) (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:16
User entered empty.	Emma Partin (b) (4) (b) (4)	25 Aug 2020 16:18:25

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:26
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:22

US3832211

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	01 Sep 2020 13:46:22

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered '1 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 01:48:50
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:31

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	01 Sep 2020 13:46:35

US3832211

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	01 Sep 2020 13:46:35

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '8 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	08 Sep 2020 14:36:04

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	08 Sep 2020 14:36:11

US3832211

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered '1'	System	08 Sep 2020 14:36:11

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:23
	(b) (4)	

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Clinic (Clinic)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT2'	System	15 Sep 2020 14:35:23

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Pre-Dose (PREDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '10:48'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 10:48'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '98.3' F	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '88'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '154'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '77'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Post-Dose (POSTDOSE)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '11:42'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:42'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '98.0' F	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '50'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '16'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '131'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	29 Sep 2020 12:37:47
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Noted as NCS as per Sub-I' (Site from System).	Danyel Johnson (b) (4) (b) (4)	23 Sep 2020 14:11:42
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '56'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	15 Sep 2020 15:54:45

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 14:35:33

US3832211

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:33

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20
	(b) (4)	

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered '11:12'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:12'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'ONCE'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 15:14:20

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '15 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:06'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:09

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 05:44:17
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' answered with 'DCF Will be created to correct reported date in PPD' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:18:31
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 17SEP2020 is reported under Visit 2 Day 29 in PPD Central lab, however the same is updated with 15SEP2020 in EDC. Please review the dates and update as required.Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:05:43
User entered '15 Sep 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '11:01' reason for change: Data Entry Error	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:33
User entered '11:06' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:07:19
User entered '11:01'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:07:33
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:19
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	11 Nov 2020 19:06:34
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty; reason for change Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	11 Nov 2020 19:06:34
User entered '11:01' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:33
User entered '11:06' reason for change: Data Entry Error	(b) (4)	
	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:07:19
User entered '11:01'	(b) (4)	
	Alyssa-Kay Peay (b) (4)	15 Sep 2020 15:02:38
	(b) (4)	

US3832211

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered empty.	System	11 Nov 2020 19:06:34
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:07:33
User entered '15 Sep 2020 11:06'	System	15 Sep 2020 15:07:19
User entered '15 Sep 2020 11:01'	System	15 Sep 2020 15:02:38

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Sep 2020 14:35:39

US3832211

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '1'	System	15 Sep 2020 14:35:39

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered 'Yes (Y)'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:13', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered '98.0'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered 'No (N)'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '185f48d3-678c-4201-92e5-e5b3429225d2'	System	15 Sep 2020 15:47:45
User entered '15 Sep 2020 11:47'	System	15 Sep 2020 15:47:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered 'Yes (Y)'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered '98.3'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:01:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered 'No (N)'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae79a706-6ced-4cbc-bea4-03b139168585'	System	16 Sep 2020 01:02:08
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:02:08

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered 'Yes (Y)'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered '98.6'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered 'No (N)'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '93a1db09-ae8f-47e2-82ba-cb417105589a'	System	16 Sep 2020 18:17:46
User entered '16 Sep 2020 14:17'	System	16 Sep 2020 18:17:46

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:36', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered 'Yes (Y)'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered '97.6'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:18:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered 'No (N)'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3732e49e-f72d-4077-80f7-bc9824a54d03'	System	17 Sep 2020 16:19:18
User entered '17 Sep 2020 12:19'	System	17 Sep 2020 16:19:18

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered 'Yes (Y)'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered '98.1'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered 'No (N)'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6ecceb34-e439-4ac4-8c1d-b671ab4c4b03'	System	18 Sep 2020 16:03:21
User entered '18 Sep 2020 12:02'	System	18 Sep 2020 16:03:21

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:48:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered 'Yes (Y)'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered '97.8'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered 'No (N)'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '793863e0-d8eb-470c-a921-a0ca4e55ef65'	System	19 Sep 2020 18:49:24
User entered '19 Sep 2020 14:49'	System	19 Sep 2020 18:49:24

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:08', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered 'Yes (Y)'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered '98.2'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered 'No (N)'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ae7e4f35-bf1a-4e35-a7e2-6cd9b7a9c953'	System	20 Sep 2020 19:07:45
User entered '20 Sep 2020 15:07'	System	20 Sep 2020 19:07:45

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:48:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered 'Yes (Y)'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered '98.5'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered 'No (N)'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'c2e96b56-4dc4-4dae-9ca0-e0cc23408f2d'	System	21 Sep 2020 19:49:47
User entered '21 Sep 2020 15:49'	System	21 Sep 2020 19:49:47

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'None (1)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'No (N)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:47:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'No (N)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered 'None (1)'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a5d923bd-e53c-45bc-8db9-5ce8babef45c'	System	15 Sep 2020 15:48:13
User entered '15 Sep 2020 11:48'	System	15 Sep 2020 15:48:13

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'None (1)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'No (N)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'No (N)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered 'None (1)'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:02:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'fdac5e29-a789-49bb-b222-f5e533067a68'	System	16 Sep 2020 01:03:01
User entered '15 Sep 2020 21:02'	System	16 Sep 2020 01:03:01

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'None (1)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'No (N)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:17:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'No (N)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered 'None (1)'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4dabc8db-0175-45d4-9002-8a81bab3d1ad'	System	16 Sep 2020 18:18:14
User entered '16 Sep 2020 14:18'	System	16 Sep 2020 18:18:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'None (1)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'No (N)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:19:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'No (N)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered 'None (1)'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b0c5e63d-733e-4cfc-9bb9-444f74d27bd9'	System	17 Sep 2020 16:20:14
User entered '17 Sep 2020 12:20'	System	17 Sep 2020 16:20:14

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'None (1)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:02:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'No (N)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'No (N)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered 'None (1)'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b565b89b-3254-42dd-9380-de0c46602a15'	System	18 Sep 2020 16:03:49
User entered '18 Sep 2020 12:03'	System	18 Sep 2020 16:03:49

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'None (1)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'No (N)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'No (N)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered 'None (1)'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:49:59', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ab38b83c-c6bf-4384-b376-ca7b4767d507'	System	19 Sep 2020 18:50:02
User entered '19 Sep 2020 14:49'	System	19 Sep 2020 18:50:02

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'None (1)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'No (N)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'No (N)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:07:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered 'None (1)'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f316fec7-ae24-405f-a3cf-aed6c7fd5d3b'	System	20 Sep 2020 19:08:08
User entered '20 Sep 2020 15:08'	System	20 Sep 2020 19:08:08

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:51', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'None (1)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:49:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'No (N)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'No (N)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered 'None (1)'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aabfac80-21b8-4916-9347-250d6a504061'	System	21 Sep 2020 19:50:19
User entered '21 Sep 2020 15:50'	System	21 Sep 2020 19:50:19

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:31', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'None (0)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered 'No (N)'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T11:48:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '804ac23b-e9d6-4944-aeb2-d4b79428ac6f'	System	15 Sep 2020 15:48:56
User entered '15 Sep 2020 11:48'	System	15 Sep 2020 15:48:56

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 11:32'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:02'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'None (0)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered 'No (N)'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-15T21:03:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9f0efb74-5ab5-46d0-98d0-53fdb63d1e06'	System	16 Sep 2020 01:03:55
User entered '15 Sep 2020 21:03'	System	16 Sep 2020 01:03:55

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '15 Sep 2020 14:57'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 2'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:25', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:35', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'None (0)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered 'No (N)'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-16T14:18:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '40af4063-683c-4588-b947-a20f13a2851c'	System	16 Sep 2020 18:18:57
User entered '16 Sep 2020 14:18'	System	16 Sep 2020 18:18:57

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 3'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:22', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'None (0)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:20:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered 'Yes (Y)'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-17T12:21:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6c864fe2-5357-48c9-967d-9ba254c0b41b'	System	17 Sep 2020 16:21:05
User entered '17 Sep 2020 12:21'	System	17 Sep 2020 16:21:05

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 4'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'None (0)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:03:56', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered 'No (N)'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-18T12:04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '981a8fd0-3fe8-49d7-b9a6-de7c252476f2'	System	18 Sep 2020 16:04:20
User entered '18 Sep 2020 12:04'	System	18 Sep 2020 16:04:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 5'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:08', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:20', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:23', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146becc4'	System	19 Sep 2020 18:50:52
User entered 'None (0)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered 'No (N)'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-19T14:50:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '382d5a18-16aa-4e88-8597-8116146beccd'	System	19 Sep 2020 18:50:52
User entered '19 Sep 2020 14:50'	System	19 Sep 2020 18:50:52

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 6'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'None (0)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered 'No (N)'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-20T15:08:38', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '063d898d-c832-4bd0-83dc-51a50169c4ff'	System	20 Sep 2020 19:08:42
User entered '20 Sep 2020 15:08'	System	20 Sep 2020 19:08:42

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	15 Sep 2020 15:14:20
User entered 'Day 7'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:47', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'None (0)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered 'No (N)'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-09-21T15:50:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'aa4ef618-d4ac-4e9d-ae8c-454003ea0abb'	System	21 Sep 2020 19:50:58
User entered '21 Sep 2020 15:50'	System	21 Sep 2020 19:50:58

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 15:14:20

US3832211

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:00:04

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 15:14:20

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '23 Sep 2020'	Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Danyel Johnson (b) (4)	23 Sep 2020 14:07:39

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	23 Sep 2020 14:07:47

US3832211

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered 'I'	System	23 Sep 2020 14:07:47

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:23:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered '29 Sep 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23
	(b) (4)	

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:23:51
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	29 Sep 2020 15:05:23

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:23:51
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	29 Sep 2020 15:05:30

US3832211

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered '1'	System	29 Sep 2020 15:05:30

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '06 Oct 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	06 Oct 2020 15:42:26

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	06 Oct 2020 15:42:31

US3832211

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:22:58
User entered '1'	System	06 Oct 2020 15:42:31

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'VISIT3'	System	13 Oct 2020 14:36:20

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '08:28'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '13 Oct 2020 08:28'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '98.1' F	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Oral (Oral)'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered empty.	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '80'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'bpm'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '17'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'breaths/min'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '146'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '65'	Emma Partin (b) (4)	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'mmHg'	System	13 Oct 2020 14:37:00

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29

US3832211

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:09

US3832211

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:09

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '13 Oct 2020'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered '08:46'	Emma Partin (b) (4)	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '13 Oct 2020 08:46'	System	13 Oct 2020 14:37:32

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	15 Feb 2021 14:24:39
User entered 'Yes (Y)'	Emma Partin (b) (4)	13 Oct 2020 14:37:43

US3832211

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered '1'	System	13 Oct 2020 14:37:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 64'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:31:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7'	System	20 Oct 2020 17:32:57
User entered 'No (N)'	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:30:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7'	System	20 Oct 2020 17:32:57
User entered 'No (N)'	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-20T13:32:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1328f857-9b39-4ec3-80f2-68e75d308fc7' User entered '20 Oct 2020 13:32:52'	System	20 Oct 2020 17:32:57
	System	20 Oct 2020 17:32:57

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 71'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:52:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9'	System	27 Oct 2020 16:53:20
User entered 'No (N)'	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:47:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9'	System	27 Oct 2020 16:53:20
User entered 'No (N)'	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-10-27T12:53:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0db3da34-6d06-49f9-8eaa-fcf16bc529c9' User entered '27 Oct 2020 12:53:15'	System	27 Oct 2020 16:53:20
	System	27 Oct 2020 16:53:20

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 78'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:26', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered 'No (N)'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered 'No (N)'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-03T11:46:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'be52bcfe-1534-4414-b730-c3bb6f55adf8'	System	03 Nov 2020 16:46:43
User entered '03 Nov 2020 11:46:37'	System	03 Nov 2020 16:46:43

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered 'Day 92'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:41:44', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered 'No (N)'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:41:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered 'No (N)'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-17T10:42:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5ef9328a-4330-4944-a71e-667fa39c01ed'	System	17 Nov 2020 15:42:18
User entered '17 Nov 2020 10:42:15'	System	17 Nov 2020 15:42:18

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 20:26:12

US3832211

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:27:01
Data entry locked.	System	18 Aug 2020 20:26:12
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 20:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[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 (e5ee6995655da022)', Time: '2020-11-22T09:30:57', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered 'No (N)'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-11-22T09:31:03', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered 'No (N)'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-22T09:31:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '4226d0de-360f-445c-b5c1-71dbaef97469'	System	22 Nov 2020 14:31:22
User entered '22 Nov 2020 09:31:17'	System	22 Nov 2020 14:31:22

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-11-30T09:47:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered 'No (N)'	System	30 Nov 2020 14:48:08

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-11-30T09:47:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered 'No (N)'	System	30 Nov 2020 14:48:08

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-11-30T09:48:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6b287e8a-01c6-43ae-aba2-37479ada500c'	System	30 Nov 2020 14:48:08
User entered '30 Nov 2020 09:48:04'	System	30 Nov 2020 14:48:08

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-12-03T17:03:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1'	System	03 Dec 2020 22:03:59
User entered 'No (N)'	System	03 Dec 2020 22:03:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-12-03T17:03:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1'	System	03 Dec 2020 22:03:59
User entered 'No (N)'	System	03 Dec 2020 22:03:59

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-03T17:03:53', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '57d233d6-3514-4115-a6fa-b51e4c8980b1'	System	03 Dec 2020 22:03:59
User entered '03 Dec 2020 17:03:53'	System	03 Dec 2020 22:03:59

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-12-10T11:43:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9'	System	10 Dec 2020 16:43:44
User entered 'No (N)'	System	10 Dec 2020 16:43:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-12-10T11:43:15', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9'	System	10 Dec 2020 16:43:44
User entered 'No (N)'	System	10 Dec 2020 16:43:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-10T11:43:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '88816bc0-dfbd-4e1c-9d93-55f73ac1a0d9'	System	10 Dec 2020 16:43:44
User entered '10 Dec 2020 11:43:40'	System	10 Dec 2020 16:43:44

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-12-17T09:53:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered 'No (N)'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-12-17T09:53:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered 'No (N)'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-17T09:53:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'dc96b05d-7784-49af-ac6d-f0f968ba0c12'	System	17 Dec 2020 14:53:54
User entered '17 Dec 2020 09:53:50'	System	17 Dec 2020 14:53:54

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-12-24T09:52:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered 'No (N)'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-12-24T09:53:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered 'No (N)'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-24T09:53:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '0a1dfc61-c35d-4656-a5ca-7e2192dcd232'	System	24 Dec 2020 14:53:16
User entered '24 Dec 2020 09:53:14'	System	24 Dec 2020 14:53:16

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2020-12-31T05:15:34', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605'	System	31 Dec 2020 10:15:50
User entered 'No (N)'	System	31 Dec 2020 10:15:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2020-12-31T05:15:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605'	System	31 Dec 2020 10:15:50
User entered 'No (N)'	System	31 Dec 2020 10:15:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2020-12-31T05:15:48', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6e0ae5a7-ccd4-4fe5-995b-1982f69db605'	System	31 Dec 2020 10:15:50
User entered '31 Dec 2020 05:15:48'	System	31 Dec 2020 10:15:50

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-01-09T22:16:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11'	System	10 Jan 2021 03:16:42
User entered 'No (N)'	System	10 Jan 2021 03:16:42

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-01-09T22:16:29', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11'	System	10 Jan 2021 03:16:42
User entered 'No (N)'	System	10 Jan 2021 03:16:42

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-09T22:16:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5e075ad4-892f-46db-a0b3-55fee65d7d11'	System	10 Jan 2021 03:16:42
User entered '09 Jan 2021 22:16:40'	System	10 Jan 2021 03:16:42

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-01-15T21:08:28', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc'	System	16 Jan 2021 02:08:50
User entered 'No (N)'	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-01-15T21:08:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc'	System	16 Jan 2021 02:08:50
User entered 'No (N)'	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-15T21:08:40', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '9a187a00-be66-4f71-9f4d-6e3be51a59dc' User entered '15 Jan 2021 21:08:40'	System	16 Jan 2021 02:08:50
	System	16 Jan 2021 02:08:50

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-01-21T12:21:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdb9c92bc'	System	21 Jan 2021 17:21:55
User entered 'No (N)'	System	21 Jan 2021 17:21:55

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-01-21T12:21:45', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdb9c92bc'	System	21 Jan 2021 17:21:55
User entered 'No (N)'	System	21 Jan 2021 17:21:55

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-21T12:21:55', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'b4ab0a0e-8987-41ae-8fde-f5bdbc9c92bc'	System	21 Jan 2021 17:21:55
User entered '21 Jan 2021 12:21:55'	System	21 Jan 2021 17:21:55

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-01-28T13:20:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'Yes (Y)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-01-28T13:20:19', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-01-28T13:20:30', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

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 (e5ee6995655da022)', Time: '2021-01-28T13:21:12', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a'	System	28 Jan 2021 18:21:31
User entered 'No (N)'	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-01-28T13:21:32', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '5b75b77c-3eca-45dc-be54-b5d7b190fd1a' User entered '28 Jan 2021 13:21:32'	System	28 Jan 2021 18:21:31
	System	28 Jan 2021 18:21:31

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-02-04T11:01:49', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered 'No (N)'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-02-04T11:02:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered 'No (N)'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-04T11:02:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '7fda08ae-cda9-4326-a279-473fca2b7952'	System	04 Feb 2021 16:02:41
User entered '04 Feb 2021 11:02:37'	System	04 Feb 2021 16:02:41

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-02-13T23:41:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe'	System	14 Feb 2021 04:41:48
User entered 'No (N)'	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-02-13T23:41:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe'	System	14 Feb 2021 04:41:48
User entered 'No (N)'	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-13T23:41:46', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '67c2a57c-02d7-4305-8ea0-dcf08a7203fe' User entered '13 Feb 2021 23:41:46'	System	14 Feb 2021 04:41:48
	System	14 Feb 2021 04:41:48

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-02-18T13:25:52', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered 'No (N)'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-02-18T13:25:58', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered 'No (N)'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-18T13:26:05', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '3d940be3-87f8-4c81-b68e-2967ba998afc'	System	18 Feb 2021 18:26:12
User entered '18 Feb 2021 13:26:05'	System	18 Feb 2021 18:26:12

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-02-25T11:27:54', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered 'No (N)'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-02-25T11:28:01', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered 'No (N)'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-25T11:28:09', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '23e54c85-d387-41d0-bb6c-9e0b5a2b57ba'	System	26 Feb 2021 03:44:19
User entered '25 Feb 2021 11:28:09'	System	26 Feb 2021 03:44:19

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-03-04T08:26:07', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered 'No (N)'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-03-04T08:26:14', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered 'No (N)'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-04T08:26:27', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '1cc8b05d-10af-42e1-b3f6-6d97625eb119'	System	04 Mar 2021 13:26:30
User entered '04 Mar 2021 08:26:27'	System	04 Mar 2021 13:26:30

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (e5ee6995655da022)', Time: '2021-03-11T14:59:04', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d'	System	11 Mar 2021 19:59:44
User entered 'No (N)'	System	11 Mar 2021 19:59:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (e5ee6995655da022)', Time: '2021-03-11T14:59:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d'	System	11 Mar 2021 19:59:44
User entered 'No (N)'	System	11 Mar 2021 19:59:44

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-03-11T14:59:41', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '6fe16e44-35be-481b-a870-66224c22c52d' User entered '11 Mar 2021 14:59:41'	System	11 Mar 2021 19:59:44
	System	11 Mar 2021 19:59:44

**US3832211**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (c9704bee637353a4)', Time: '2021-03-25T13:14:39-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca'	System	25 Mar 2021 17:15:04
User entered 'No (N)'	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (c9704bee637353a4)', Time: '2021-03-25T13:14:44-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca'	System	25 Mar 2021 17:15:04
User entered 'No (N)'	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-03-25T13:14:54-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'f0ae954c-fd36-4eb1-a49e-436f6cabfdca' User entered '25 Mar 2021 13:14:54'	System	25 Mar 2021 17:15:04
	System	25 Mar 2021 17:15:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (c9704bee637353a4)', Time: '2021-04-05T15:16:26-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered 'No (N)'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (c9704bee637353a4)', Time: '2021-04-05T15:16:30-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered 'No (N)'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c9704bee637353a4)', Time: '2021-04-05T15:16:42-04:00', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'ad1055de-6be8-4fe8-8842-e49779e471d1'	System	05 Apr 2021 19:16:51
User entered '05 Apr 2021 15:16:42'	System	05 Apr 2021 19:16:51

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:11', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68' User entered 'No (N)'	System	12 Apr 2021 19:14:24
	System	12 Apr 2021 19:14:24

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:16', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68'	System	12 Apr 2021 19:14:24
User entered 'No (N)'	System	12 Apr 2021 19:14:24

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-12T15:14:21', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'a286b85a-b0f6-4be7-96ee-8e713f808d68' User entered '12 Apr 2021 15:14:21'	System	12 Apr 2021 19:14:24
	System	12 Apr 2021 19:14:24

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:10', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4'	System	15 Apr 2021 14:01:40
User entered 'No (N)'	System	15 Apr 2021 14:01:40

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:24', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4'	System	15 Apr 2021 14:01:40
User entered 'No (N)'	System	15 Apr 2021 14:01:40

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-15T10:00:43', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'effc7ad5-70d0-472b-98df-6c7ba6f14ab4' User entered '15 Apr 2021 10:00:43'	System	15 Apr 2021 14:01:40
	System	15 Apr 2021 14:01:40

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:56:33', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered 'No (N)'	System	22 Apr 2021 14:57:23
	System	22 Apr 2021 14:57:23

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:56:37', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered 'No (N)'	System	22 Apr 2021 14:57:23
	System	22 Apr 2021 14:57:23

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-22T10:57:18', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'de9de251-cf60-4eaf-8ca5-fddf2e8d082b' User entered '22 Apr 2021 10:57:18'	System	22 Apr 2021 14:57:23
	System	22 Apr 2021 14:57:23

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:23:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf'	System	29 Apr 2021 16:24:47
User entered 'No (N)'	System	29 Apr 2021 16:24:47

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

Have you been exposed to someone with 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 (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:23:42', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf' User entered 'No (N)'	System	29 Apr 2021 16:24:47
	System	29 Apr 2021 16:24:47

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (02388721-5CA1-4B62-BC78-B25400A33B54)', Time: '2021-04-29T12:24:17', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: '27c6a147-d232-46c7-a400-825263b17bdf' User entered '29 Apr 2021 12:24:17'	System	29 Apr 2021 16:24:47
	System	29 Apr 2021 16:24:47

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

**TIMEPOINT**

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:30:04

**US3832211**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:00:04**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:30:04

US3832211

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:00:04

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:30:04
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:30:04

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:04

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 19:47:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-27T18:35:39', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'e18b7048-aaa9-49c8-bb70-95d12cb2c49c'	System	27 Feb 2021 23:35:51
User entered 'No (N)'	System	27 Feb 2021 23:35:51

US3832211

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 10:00:04

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 19:47:32
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (e5ee6995655da022)', Time: '2021-02-27T18:35:50', User OID: 'PatientReportedOutcome (US3832211)', ODM File OID: 'e18b7048-aaa9-49c8-bb70-95d12cb2c49c' User entered '27 Feb 2021 18:35:50'	System	27 Feb 2021 23:35:51
	System	27 Feb 2021 23:35:51

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '10 Nov 2020'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	10 Nov 2020 17:20:12

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	10 Nov 2020 17:20:23

US3832211

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 14:23:29
User entered 'I'	System	10 Nov 2020 17:20:23

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '11 Dec 2020'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:16

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	11 Dec 2020 16:49:20

US3832211

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User entered 'I'	System	11 Dec 2020 16:49:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '11 Jan 2021'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20

US3832211

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:20
	(b) (4)	

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	11 Jan 2021 14:43:24

US3832211

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:04
User entered '1'	System	11 Jan 2021 14:43:24

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15 Feb 2021'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42

US3832211

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:42
	(b) (4)	

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	15 Feb 2021 16:00:48

US3832211

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 17:05:06
User entered '1'	System	15 Feb 2021 16:00:48

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51
	(b) (4)	

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51
	(b) (4)	

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Clinic (Clinic)'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:52:51
	(b) (4)	

US3832211

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered 'VISIT4'	System	12 Apr 2021 16:52:51

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered empty.	System	12 Apr 2021 16:53:22

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18

US3832211

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:53:42

US3832211

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:53:42

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:08
	(b) (4)	

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '10:17'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered '23 Mar 2021 10:17'	System	12 Apr 2021 16:54:08

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:15
	(b) (4)	

US3832211

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:14:18
User entered '1'	System	12 Apr 2021 16:54:15

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:54:27

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
	(b) (4)	
User entered '12 Apr 2021'	Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Rodolfo Barrera (b) (4)	12 Apr 2021 16:54:27
	(b) (4)	

US3832211

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:54:27

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4) (b) (4)	12 Apr 2021 16:54:35

US3832211

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

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Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 16:54:35

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US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 21:07:00

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0'	Rodolfo Barrera (b) (4)	08 Apr 2021 13:11:57
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:02:12

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
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). User signature succeeded.	(b) (4), (b) (6) Gowdhami Mohan (b) (4)	16 Apr 2021 01:54:14 12 Apr 2021 23:15:53
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 13:12:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Rodolfo Barrera (b) (4)	08 Apr 2021 13:11:57
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 11:09:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:02:12

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:38:51
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 07:38:51
User entered 'Placebo (Placebo)'	Emma Partin (b) (4)	19 Jan 2021 21:08:21
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '1'	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 10:00:04

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '1'	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:04'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:04'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '97.8' F	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '74'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'bpm'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '14'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'breaths/min'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '113'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '65'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '72.5' in	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '218' lb	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:00:04

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '29.22068'	System	19 Jan 2021 22:18:02
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:43'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:43'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '98.8' F	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Oral (Oral)'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02
	(b) (4)	

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '75'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'bpm'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16'	Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'breaths/min'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '130'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '77'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mmHg'	System	19 Jan 2021 22:18:02

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:08:35

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:35

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'mRNA-1273'	System	19 Jan 2021 21:23:41
DataPoint set to visible.	System	19 Jan 2021 21:08:21

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '16:13'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 16:13'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Left Arm (LEFT ARM)'	Emma Partin (b) (4)	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'ONCE'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered 'INTRAMUSCULAR'	System	19 Jan 2021 21:23:41

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15:50'	(b) (4) Emma Partin (b) (4)	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 15:50'	System	19 Jan 2021 21:07:40

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '19 Jan 2021'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '15:48'	Emma Partin (b) (4)	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 10:00:04

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '19 Jan 2021 15:48'	System	19 Jan 2021 21:08:11

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Emma Partin (b) (4)	19 Jan 2021 21:08:28

US3832211

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:54:29
User entered '1'	System	19 Jan 2021 21:08:28

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '26 Jan 2021'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15

US3832211

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered empty.	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:15

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	26 Jan 2021 17:31:18

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User entered '1'	System	26 Jan 2021 17:31:18

US3832211

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 19:35:08
User entered '1'	System	26 Jan 2021 17:31:18
DataPoint set to visible.	System	26 Jan 2021 17:31:18

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:37
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Clinic (Clinic)'	Emma Partin (b) (4)	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'OLD29'	System	17 Feb 2021 15:08:37

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User accepted default value 'Pre-Dose (PREDOSE)'	Emma Partin (b) (4) (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '09:40'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 09:40'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '97.9' F	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '79'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'bpm'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '13'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'breaths/min'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '111'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '66'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User accepted default value 'Post-Dose (POSTDOSE)'	Emma Partin (b) (4) (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10:18'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 10:18'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '97.9' F	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (Oral)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '81'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'bpm'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '14'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'breaths/min'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '118'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '70'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:00:04

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mmHg'	System	17 Feb 2021 15:24:49

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:43

US3832211

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:08:43
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

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)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'mRNA-1273'	System	17 Feb 2021 15:09:00
DataPoint set to visible.	System	26 Jan 2021 17:31:18

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '17 Feb 2021'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00
	(b) (4)	

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '09:46'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '17 Feb 2021 09:46'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'ONCE'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:00:04

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered 'INTRAMUSCULAR'	System	17 Feb 2021 15:09:00

US3832211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Emma Partin (b) (4)	17 Feb 2021 15:09:05

US3832211

Folder: OL-D29 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 03:31:40
User entered '1'	System	17 Feb 2021 15:09:05

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered '24 Feb 2021'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered 'Contact Made (CONTACT MADE)'	Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46

US3832211

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 10:00:04

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User signature succeeded.	Gowdhami Mohan (b) (4)	08 Mar 2021 12:11:39
User entered empty.	(b) (4) Rodolfo Barrera (b) (4)	24 Feb 2021 17:09:46
	(b) (4)	

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User closed query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 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.	(b) (4), (b) (6)	08 Apr 2021 15:21:57
' (Site from DM). Query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 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.	Danyel Johnson (b) (4) (b) (4)	06 Apr 2021 19:42:40
' answered with 'Updated per review of source ' (Site from DM). User opened query 'Per GCL Lab Recon: Immuno: Per Preclarus report, Sample dated 23 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.	(b) (4), (b) (6)	06 Apr 2021 08:55:28
' (Site from DM). User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	08 Mar 2021 12:11:39
User entered 'Yes (Y)'	Rodolfo Barrera (b) (4) (b) (4)	24 Feb 2021 17:09:51

US3832211

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:00:04

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 23:40:14
User entered '1'	System	24 Feb 2021 17:09:51

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[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 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Clinic (Clinic)'	Danyel Johnson (b) (4)	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:00:04

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered 'OLD57'	System	06 Apr 2021 19:14:10

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27
	(b) (4)	

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered empty.	System	06 Apr 2021 19:14:27

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56

US3832211

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:00:04

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:15:06
	(b) (4)	

US3832211

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:00:04

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:15:06

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'Yes (Y)'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:15:33

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '23 Mar 2021'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:15:33
	(b) (4)	

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '10:17'	(b) (4) Danyel Johnson (b) (4)	06 Apr 2021 19:15:33

US3832211

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 10:00:04

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:13:56
User entered '23 Mar 2021 10:17'	System	06 Apr 2021 19:15:33

US3832211

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 10:00:04

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:36:05
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:43:00

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	27 Oct 2020 23:54:18
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:23
User entered	System	14 Oct 2020 13:41:15
'USA-US100-2020-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 13:41:15

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Chronic obstructive pulmonary disease, LLT: COPD exacerbation - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:52:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Oct 2020 13:52:29
Data point term sent to Coder	System	13 Oct 2020 13:51:24
User entered 'COPD Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'No (N)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '8 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AE start date and time \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 13:51:06

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US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:02
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
User entered 'No (N)' reason for change: New Information	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 23:33:22
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' answered with 'Data is entered as correct as reported' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	26 Apr 2021 14:38:54
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 14:29:40
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:14:04
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
User entered '16 Oct 2020' reason for change: New Information	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:37:53
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty; reason for change New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 00:13:16
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:17
User entered empty.	System	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Yes (Y)' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
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)	15 Oct 2020 06:42:06
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 'admission dates are entered as 08 OCT 2020- 09 OT 2020' (Site from System).	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:55:11
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	13 Oct 2020 21:54:15
User entered '1' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '8 Oct 2020' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '9 Oct 2020' reason for change: New Information	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 21:54:15
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Oct 2020 21:54:15
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 21:54:15
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Oct 2020 13:51:06
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered 'Not Applicable (NOT APPLICABLE)'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

None

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Jan 2021 19:16:38
User closed query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 14:28:51
Query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'Data updated per subject report' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:38:13
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Danyel Johnson (b) (4)	12 Nov 2020 14:37:53
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:23
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User opened query 'PV Query: Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:56:53
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: New Information	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06
	(b) (4)	

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:16:40
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:50:25
DataPoint Un-verified.	(b) (4), (b) (6)	13 Apr 2021 20:01:17
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 20:01:11
User closed query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 13:50:38
Query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' answered with 'Reviewed and updated per review' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:46:33
User opened query 'Per DM CLR: Narrative indicates that the subject was treated with O2 at 4L. However, there is no recorded ConMed that match this treatment. Please update to record the corresponding treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Mar 2021 19:11:17
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User entered '76 Y/O RANDOMIZED MALE WHO RECEIVED THE FIRST DOSE OF BLINDED MRNA-1273 OR PLACEBO FOR SARS-COV-2 VACCINATION ON 8/18/2020 AND HIS SECOND, FINAL DOSE OF STUDY DRUG, ON 09/15/ 2020. PRESENTED TO THE ER ON 10/8/2020 WITH WORSENING OF SHORTNESS OF BREATH PER ER RECORDS SPO2 WAS AT 75% PRIOR TO O2 ADMINISTRATION UPON ADMISSION SPO2 WAS AT 94%. SUBJECT STATES HE WAS SEEN BY HIS PULMONOLOGIST 10/7/2020 AND WAS DIAGNOSED WITH A COPD EXACERBATION THE SUBJECT WAS TREATED WITH , PREDNISONE, AND O2 AT 4L. SUBJECT WAS ADMITTED AND TREATED WITH BENZONATATE 200MG TID PRN X7 DAYS, DOXYCYCLINE 100MG 1 PO BID X 7 DAYS, GUAIFENESIN 600MG BID X 7 DAYS IPRATROPIUM-ALBUTEROL 20-100MCG 1 PUFF QID, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. COVID TESTING AS WELL AS INFLUENZA A AND B TESTING COMPLETED BOTH WITH NEGATIVE RESULTS. CHEST XRAY COMPLETED RESULTS WITHIN NORMAL LIMITS.' reason for change: New Information	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:03:51
User closed query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:47:49

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' answered with 'Review of records indicate prednisone and O2 however the subject was given Doxycycline and not levaquin, levaquin was reported in error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:09:16
User opened query 'Per DM CLR: Narrative indicates that the subject received Levaquin, Prednisone and Oxygen at 4 L/min rate. However, there is no corresponding ConMed record that match these information. Please review and update to record the corresponding medications as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6) [REDACTED]	03 Dec 2020 02:41:01
User closed query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.)' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	13 Nov 2020 14:29:12
User closed query 'PV Query: Please add treatment medications to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	13 Nov 2020 14:29:07
User closed query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	13 Nov 2020 14:29:00
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) [REDACTED]	13 Nov 2020 14:28:56
Query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.)' answered with 'Per review of records none identified ' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:42:23
Query 'PV Query: Please add treatment medications to concomitant medication eCRF.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:42:05

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' answered with 'Per records the only symptom reported was shortness of breath' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:41:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' answered with 'Updated' (Site from Safety).	Danyel Johnson (b) (4)	12 Nov 2020 14:41:31
User entered '76 y/o randomized male who received the first dose of blinded mRNA-1273 or placebo for SARS-CoV-2 vaccination on 8/18/2020 and his second, final dose of study drug, on 09/15/ 2020. Presented to the ER on 10/8/2020 with worsening of shortness of breath per ER records SpO2 was at 75% prior to O2 administration upon admission SpO2 was at 94%. Subject states he was seen by his pulmonologist 10/7/2020 and was diagnosed with a COPD exacerbation the subject was treated with Levaquin, Prednisone, and O2 at 4l. Subject was admitted and treated with Benzonatate 200mg TID prn X7 days, doxycycline 100mg 1 po bid x 7 days, Guaifenesin 600mg bid X 7 days Ipratropium-albuterol 20-100mcg 1 puff qid, Prednisone taper 40mg X3 days , 20mg for 3 days, 10mg for 3 days. COVID testing as well as Influenza A and B testing completed both with negative results. Chest xray completed results within normal limits.' reason for change: New Information	Danyel Johnson (b) (4)	12 Nov 2020 14:41:19
DataPoint Un-verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:54:18
User opened query 'PV query: Please report if there was an identified trigger for the COPD exacerbation (ie. infection, medication noncompliance, etc.).' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:59:02
User opened query 'PV Query: Please add treatment medications to concomitant medication eCRF.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:58:40

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide initial signs and symptoms experienced by patient, along with oxygen saturation levels.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:43
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results (including CXR if performed). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Oct 2020 16:57:01
User entered 'SUBJECT REPORTED TO STAFF THAT HE WAS HOSPITALIZED FROM 08 OCT 2020 THROUGH 09 OCT 2020 FOR LESS THAN 24 HOURS. SUBJECT REPORTED THAT HE HAD LOW OXYGEN LEVELS UPON ADMISSION TO THE HOSPITAL. SUBJECT REPORTS THAT HE WAS GIVEN MEDICATIONS IN THE HOSPITAL AND UPON DISCHARGE, BUT WASN'T SURE OF THE NAMES OF THE MEDICATIONS OR THE DOSES. SUBJECT SIGNED A MEDICAL RECORDS RELEASE FORM DURING OFFICE VISIT. SITE TO REQUEST RECORDS. SUBJECT INSTRUCTED TO FOLLOW UP WITH SITE WITH ANY WORSENING OF CONDITIONS. SITE TO CONTINUE TO MONITOR.'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 21:54:15

SAE Follow Up #1: Records received and reviewed by site staff. Subject was admitted to the hospital on 08 OCT 2020 at 12:39 AM and discharged on 09 OCT 2020 at 10:49 AM. Subject was hospitalized for greater than 24 hours changing the AE to an SAE. Subject tested negative for Flu A, Flu B, and COVID-19. Subject's exacerbation was treated with nebulized medications, steroids, and antibiotics during hospitalization. Subject stabilized and discharged home with prescriptions for benzonatate, doxycycline, Guaifenesin, Combivent Respimat, and prednisone taper. Subject was not clear on the start date of the prednisone taper, or current dose. Site to request additional records for clarification.' reason for change: New Information

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject reported to staff that he was hospitalized from 08 OCT 2020 through 09 OCT 2020 for less than 24 hours. Subject reported that he had low oxygen levels upon admission to the hospital. Subject reports that he was given medications in the hospital and upon discharge, but wasn't sure of the names of the medications or the doses. Subject signed a medical records release form during office visit. Site to request records. Subject instructed to follow up with site with any worsening of conditions. Site to continue to monitor.'	Alyssa-Kay Peay (b) (4)	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 21:54:15
User entered '0'	System	13 Oct 2020 13:51:06

US3832211

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:00:04

Medically Attended AE Derived (CSA Programming Field Only)

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Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 13:51:06

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:00:04

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:51:47
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Thank you for the update. Please respond once updated.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 00:42:53
Query 'Thank you for the update. Please respond once updated.' answered with 'Data has been updated' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 21:17:15
User opened query 'Thank you for the update. Please respond once updated.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:44:08
User closed query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	29 Oct 2020 19:44:08
Query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' answered with 'Per subject report medications are unknow site is awaiting records to update data ' (Site from CRA).	Danyel Johnson (b) (4) (b) (4)	22 Oct 2020 20:58:15
User opened query 'Per ETRTR: According to SAE "COPD Exacerbation" page, medication was dosed for SAE. Please add Medication dosing details for SAE "COPD Exacerbation" within ConMeds page, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 21:42:25
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:56:06

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL SULFATE, PRODUCTSYNONYM: ALBUTEROL SULFATE HFA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:10:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:10:18
Data point term sent to Coder	System	19 Aug 2020 10:58:23
User entered 'Albuterol Sulfate HFA'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered '90'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 10:57:33
User entered 'un Jun 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:01:24
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:57:33

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 10:57:33

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:59:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 10:59:20
Data point term sent to Coder	System	19 Aug 2020 10:58:21
User entered 'Carvedilol'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:46
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:47
User entered 'Hypertension'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:53
User entered '3.125'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:03:54
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:02
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Frequency entered does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:49:41
Query 'Per source, Frequency entered does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:42
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:32
User entered 'twice daily (BID)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:52:32
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User opened query 'Per source, Frequency entered does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:03:20
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:03
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:14
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:15
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 10:58:20
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:19
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:22
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:04:26
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:58:20

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	04 Nov 2020 13:52:32
User entered '1'	System	19 Aug 2020 10:58:20

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:58:20

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 10:58:20

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:02
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:00:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:00:19
Data point term sent to Coder User entered 'Vitamin D3'	System Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:24 19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:59:37
Query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' answered with 'Verified and updated' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 00:05:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:07:51
User opened query 'Per DM CLR: Indication=SUPPLEMENT. However, Prophylaxis was noted as 'No'. Please update eCRF as appropriate.' (Site from DM). User entered 'No (N)'	(b) (4) Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:07:39
	(b) (4), (b) (6)	29 Sep 2020 10:17:11
	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:04
User entered 'Supplement'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:06
User entered '5000'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 11:59:39
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:08:13
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'UPdated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 19:14:39
User entered 'IU (IU)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	15 Oct 2020 19:14:32
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:22:26
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:17
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:08:22
User entered 'once daily (QD)'	(b) (4), (b) (6)	
	Alyssa-Kay Peay (b) (4)	19 Aug 2020 10:59:07
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:23
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:24
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:26
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:27
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 10:59:07
User entered 'un UNK 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:42
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:43
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:45
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:08:46
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 10:59:07

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:59:07

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 10:59:07

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 10:59:07

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: DUONEB - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Aug 2020 11:02:21
Data point term sent to Coder	System	19 Aug 2020 11:01:25
User entered 'Duoneb'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered '3'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'mL (mL)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:00:31
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered '0'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered empty.	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:03
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:09:53
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:00:31
	(b) (4)	

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:00:31

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
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) (b) (4)	19 Aug 2020 11:02:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:02:20
Data point term sent to Coder	System	19 Aug 2020 11:01:25
User entered 'Eliquis'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Atrial Fibrillation'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '5'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Frequency does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:45
Query 'Per source, Frequency does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 14:42:54
User entered 'twice daily (BID)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	29 Oct 2020 14:42:39
User opened query 'Per source, Frequency does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:14:44
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:12:10
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:00:59
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:00:59

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	29 Oct 2020 14:42:39
User entered '1'	System	19 Aug 2020 11:00:59

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:00:59

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:00:59

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: TESTOSTERONE-5-ALPHA REDUCTASE INHIBITORS, PRODUCT: FINASTERIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:12:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:12:33
Data point term sent to Coder	System	19 Aug 2020 11:02:25
User entered 'Finasteride'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Benign prostatic hyperplasion'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '5'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:01:30
User entered 'un UNK 2018'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:01:30

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:01:30

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:01:30

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:01:30

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:03:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:03:24
Data point term sent to Coder	System	19 Aug 2020 11:02:25
User entered 'Gabapentin'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:02:00
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:58:09
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of NEUROPATHY. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:22:56
User entered 'Neuropathy'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:57
Query 'Per source, dose per administration does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:53:34
User entered '800' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:53:25
User opened query 'Per source, dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:17:51
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:16:46
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '600'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:57:38
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Reviewed and updated per subject report' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:17
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:00
User entered 'UN UNK 2011' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:48:00
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition (UN UNK 2011). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:26:09
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:02:00
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:00

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '3'	System	19 Aug 2020 11:02:00

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:02:00

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:02:00

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:04:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:04:25
Data point term sent to Coder	System	19 Aug 2020 11:03:26
User entered 'Humalog'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Diabetes Type II'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'units/ml'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Subcutaneous (SUBCUTANEOUS)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:02:36
User entered 'un UNK 2015'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:02:36

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

---

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:02:36

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:12:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 12:12:33
Data point term sent to Coder	System	19 Aug 2020 11:03:27
User entered 'hydrocodone-acetaminophen'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 11:58:44
User opened query 'Per DM CLR: Please update the indication to reflect the location of CHRONIC PAIN. Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:24:31
User entered 'Chronic Pain'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '10/325'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:03:17
User entered 'un Jan 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:03:17

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 11:03:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:03:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:03:17

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:05:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:05:15
Data point term sent to Coder	System	19 Aug 2020 11:04:27
User entered 'Levothyroxine'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Hypothyroidism'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'ug (ug)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:04:17
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:17

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:04:17

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:06:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:06:19
Data point term sent to Coder	System	19 Aug 2020 11:05:28
User entered 'Montelukast'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Allergic Rhinitis'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '10'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:04:46
User entered 'un May 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:04:46

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:46

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:04:46

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:04:46

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	28 Oct 2020 00:11:36
	(b) (4), (b) (6)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 19:19:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 19:19:31
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 19:18:24
Data point term sent to Coder	System	15 Oct 2020 19:16:18
Coding entries removed.	Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:16:10
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Aug 2020 23:50:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Aug 2020 23:50:16
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 11:05:30
User entered 'Nitroglycerin'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:17
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:04
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:16:21
User entered 'Angina' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:16:10
User opened query 'Per DM CLR: Please update the indication to reflect the type of CHEST PAIN (e.g. cardiac, non-cardiac). Please reconcile with the AE and Med History eCRFs as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 10:24:57
User entered 'Chest Pain'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '.4'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	15 Oct 2020 19:17:23
User entered 'Other (OTHER)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:17:23
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	19 Aug 2020 11:05:17
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'sublingual'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:05:17
User entered 'un UNK 2010'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:17

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:05:17

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:07:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 11:07:16
Data point term sent to Coder	System	19 Aug 2020 11:06:30
User entered 'Ropinirole'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:05:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Restless leg syndrome'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:05:44
User entered 'un UNK 2017'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:05:44

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:05:44

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:05:44

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:05:44

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:41:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 15:41:29
Data point term sent to Coder	System	19 Aug 2020 11:06:31
User entered 'Setraline'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Depression'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per source, Dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:59:17
Query 'Per source, Dose per administration does not match. Please review and reconcile.' answered with 'Verified and updated' (Site from CRA).	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:57:37
User entered '50' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	04 Nov 2020 13:57:27
User opened query 'Per source, Dose per administration does not match. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	28 Oct 2020 00:26:42
DataPoint Un-verified.	(b) (4), (b) (6)	28 Oct 2020 00:26:14
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '25'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:06:23
User entered 'un UNK 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:06:23

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:06:23

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:06:23

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:06:23

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:08:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:08:16
Data point term sent to Coder User entered 'Symbicort'	System Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:32 19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Chronic obstructive pulmonary disease'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:17
Query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:43
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:30
User entered '160/4.5' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	05 Nov 2020 19:29:30
User opened query 'Per DM CLR : Please note that numeric doses, if known, are preferred over "2 puff." Please provide the actual dose for this medication as there are multiple dosage options for this combination medication. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:15:23
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 13:15:23
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:15

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of puffs as there are various dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM). User entered '2'	(b) (4), (b) (6)	29 Sep 2020 10:25:36
	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
DataPoint Un-verified.	Alyssa-Kay Peay (b) (4)	05 Nov 2020 19:29:30
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	05 Nov 2020 19:29:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'puff (PUFF)' reason for change: Data Entry Error	Alyssa-Kay Peay (b) (4)	15 Oct 2020 19:20:00
	(b) (4)	
User entered 'Other (OTHER)'	Alyssa-Kay Peay (b) (4)	19 Aug 2020 11:07:24
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:00:18
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 00:11:36
Query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' answered with 'Verified and updated' (Site from DM).	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:23
User entered empty; reason for change Data Entry Error	Alyssa-Kay Peay (b) (4) (b) (4)	15 Oct 2020 19:20:00
User opened query 'Per CDM: "Dose Unit" field has an option as "Puff". Please consider removing data from this field and update the "Dose Unit" field as "Puff".' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:49:31
User entered 'puffs'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:07:24
User entered 'un UNK 2014'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:24

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 11:07:24

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:24

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:07:24

---

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:19
Data point term sent to Coder	System	19 Aug 2020 11:08:32
User entered 'Tamsulosin'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Benign prostatic hyperplasia'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '.4'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:07:56
User entered 'un UNK 2016'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:07:56

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:56

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 11:07:56

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 11:07:56

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: TRAZODONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 11:09:20
Data point term sent to Coder	System	19 Aug 2020 11:08:33
User entered 'Trazodone'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Insomnia'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '50'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'as needed (PRN)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:47
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	19 Aug 2020 11:08:22
User entered 'un UNK 2019'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 00:11:36
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	19 Aug 2020 11:08:22

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 11:08:22

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 06:45:02
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 Nov 2020 06:45:02
Data point term sent to Coder	System	02 Nov 2020 18:04:29
User entered 'Atorvastatin'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:58:12
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Reviewed and updated ' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 20:50:20
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:13
User entered 'Hyperlipidemia'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:03:43

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '80'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'once daily (QD)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'UN UNK 2012'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:03:43
	(b) (4)	

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:03:43

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:03:43

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

---

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:03:43

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	(b) (4) Codel Import (b) (4) (b) (4)	15 Dec 2020 16:53:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Codel Import (b) (4) (b) (4)	15 Dec 2020 16:53:51
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:25 14 Dec 2020 21:13:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\202003.	Codel Import (b) (4) (b) (4)	05 Nov 2020 06:54:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Codel Import (b) (4) (b) (4)	05 Nov 2020 06:54:09
Data point term sent to Coder User entered 'Meloxicam'	System Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:07:33 02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 10:58:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Reviewed and updated' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:10
User entered 'OSTEOARTHRITIS Bilateral extremities' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:00
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:23
User entered 'Osteoarthritis'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:06:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '15'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'UN UNK 2017'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered '0'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered empty.	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:00:04**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
	(b) (4)	
User entered 'No (N)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:06:32
	(b) (4)	

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:06:32

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:06:32

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:06:32

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS, EXCL. COMBINATIONS WITH EXPECTORANTS, ATC: OTHER COUGH SUPPRESSANTS, PRODUCT: BENZONATATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:14:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 05:14:14
Data point term sent to Coder	System	02 Nov 2020 18:10:39
User entered 'Benzonatate'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:49
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:47
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:51
User entered '200'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:54
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:55
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:14:58
User entered 'three times daily (TID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:02
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:06
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:08
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:12
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:14
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:16
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:00:55
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:18
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:00:55
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:53:14
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Dec 2020 10:05:47
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' answered with 'Data entry error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:44
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:34
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:13:34
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:20
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '3'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '1'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:24
User entered '804 (804)'	System	02 Nov 2020 18:10:24

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 12:52:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	03 Nov 2020 12:52:17
Data point term sent to Coder	System	02 Nov 2020 18:18:49
User entered 'Doxycycline'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:30
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:31
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:36
User entered '100'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:37
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:39
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:40
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:42
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:44
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:45
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:48
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:51
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:54
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:04
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:15:55
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:04
User entered empty.	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:16
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:05:52
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' answered with 'data entry error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:14:16
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:14:06
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:14:06
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:27:56
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:15:57
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '2'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '1'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:32
User entered '804 (804)'	System	02 Nov 2020 18:18:09

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 20:35:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Dec 2020 20:35:48
Data point term sent to Coder Coding entries removed.	System Danyel Johnson (b) (4)	14 Dec 2020 21:15:28 14 Dec 2020 21:14:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: EXPECTORANTS, EXCL. COMBINATIONS WITH COUGH SUPPRESSANTS, ATC: EXPECTORANTS, PRODUCT: GUAIFENESIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 05:32:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 05:32:21
Data point term sent to Coder	System	02 Nov 2020 18:19:50
User entered 'Guaifenesin'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:05
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:24:16
DataPoint Un-verified.	Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
User entered 'CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION' reason for change: Data Entry Error	(b) (4) Danyel Johnson (b) (4)	14 Dec 2020 21:14:59
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:07
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:10
User entered '600'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:11
User entered 'mg (mg)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:13
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:16
User entered 'twice daily (BID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:18
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:19
User entered 'Oral (ORAL)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:22
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:24
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:28
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:30
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4)	12 Nov 2020 16:02:35
User entered 'Yes (Y)'	(b) (4) Alyssa-Kay Peay (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:33
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:02:35
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	12 Nov 2020 16:02:21
User entered '16 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 16:02:21
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:32
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:05:56
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' answered with 'Data entry error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:15:13
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:14:59
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:14:59
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:28:03
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:34
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '2'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '1'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:38
User entered '804 (804)'	System	02 Nov 2020 18:19:35

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
User closed query 'please confirm levaquin should be entered.' (Site from CRA).	(b) (4), (b) (6)	22 Feb 2021 17:52:02
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
Query 'please confirm levaquin should be entered.' answered with 'Based on review of records and with subject Levaquin was never started Levaquin' (Site from CRA).	(b) (4) Danyel Johnson (b) (4)	19 Feb 2021 17:23:51
User opened query 'please confirm levaquin should be entered.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 15:31:32
User closed query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	16 Feb 2021 15:31:32
Query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' answered with 'Reviewed and updated' (Site from CRA).	Danyel Johnson (b) (4)	09 Feb 2021 15:40:26
User opened query 'per SAE note in EDC, subject took LEVAQUIN, PREDNISONE, PREDNISONE TAPER 40MG X3 DAYS , 20MG FOR 3 DAYS, 10MG FOR 3 DAYS. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 19:26:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:16:39
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM BROMIDE;SALBUTAMOL SULFATE, PRODUCTSYNONYM: COMBIVENT RESPIMAT - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 05:21:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	03 Nov 2020 05:21:14

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	02 Nov 2020 18:23:58
User entered 'Combivent Respimat (Ipratropium Albuterol)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:41
User entered 'No (N)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:43
User entered 'Adverse Event - Chronic Obstructive Pulmonary Disease Exacerbation'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:45
User entered '1'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:47
User entered 'puff (PUFF)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:49
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:51
User entered 'four times daily (QID)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:53
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:55
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:56
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:16:59
User entered '9 Oct 2020'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:01
User entered '0'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Feb 2021 09:14:04
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'Subject continued medication as treatment for COPD' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:01:43
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 20:02:00
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:02
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:05
User entered empty.	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 19:22:40
User closed query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:06:02
Query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' answered with 'Data entry error' (Site from DM).	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:15:40
DataPoint Un-verified.	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:15:29
User entered 'No (N)' reason for change: Data Entry Error	Danyel Johnson (b) (4) (b) (4)	14 Dec 2020 21:15:29
User opened query 'Per DM CLR: Was this medication taken for solicited event? = YES, however, the noted indication is not one of the listed solicited events per protocol. Please confirm and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 08:28:10
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:17:06
User entered 'Yes (Y)'	Alyssa-Kay Peay (b) (4) (b) (4)	02 Nov 2020 18:23:32

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:00:04**

[Separate Dosage Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '4'	System	02 Nov 2020 18:23:32

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

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Audit	User	Time (GMT)
User entered '1'	System	02 Nov 2020 18:23:32

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US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Definition \(derived\)](#)

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Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Nov 2020 18:23:32

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US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:24
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:48
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISONONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:57:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:57:47
Data point term sent to Coder User entered 'Prednisonone'	System Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:57:30 09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:27
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:30
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '40'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:33
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:43
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:45
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:48
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:50
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:51
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:54:53
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '1'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '1'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:49
User entered '804 (804)'	System	09 Feb 2021 15:56:41

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:02
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
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 Apr 2021 07:56:49
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
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)	09 Feb 2021 15:58:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 15:58:47
Data point term sent to Coder User entered 'Prednisone'	System Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 15:58:30 09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:04
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:07
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '20'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:09
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:10
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:13
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:15
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:20
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:23
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '11 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:24
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:32
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '13 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:55:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '1'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '1'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:57:55
User entered '804 (804)'	System	09 Feb 2021 15:57:44

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:14
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:56:49
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 Apr 2021 07:56:49
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	21 Feb 2021 21:35:22
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)	09 Feb 2021 16:17:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 16:17:56
Data point term sent to Coder	System	09 Feb 2021 16:01:02
User entered 'Prednisone'	Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:15
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:17
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'COPD Exacerbation'	(b) (4) Danyel Johnson (b) (4) (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:19
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '10'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:22
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'mg (mg)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:29
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:31
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'once daily (QD)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:33
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:36
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Oral (ORAL)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:38
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered empty.	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:40
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '14 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:42
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '0'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:56:44
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User signature succeeded.	Gowdhami Mohan (b) (4)	29 Apr 2021 02:21:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:33:25
User closed query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:33:04
Query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' answered with 'Corrected per source' (Site from CRA).	Danyel Johnson (b) (4)	21 Apr 2021 19:27:44
Signature has been broken.	Danyel Johnson (b) (4)	21 Apr 2021 19:27:14
User entered '14 Oct 2020' reason for change: Data Entry Error	Danyel Johnson (b) (4)	21 Apr 2021 19:27:14
User opened query 'Please review source and revise if needed. Source states that the end date for this Con Med is 14Oct2020.' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 19:57:18
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered '16 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:57:20
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '1'	System	09 Feb 2021 16:00:51

US3832211

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 10:00:04**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '1'	System	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:00
User entered '804 (804)'	System	09 Feb 2021 16:00:51

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User closed query 'Please add to Con Med Log in Source so data can be verified.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:56:41
Query 'Please add to Con Med Log in Source so data can be verified.' answered with 'Added per review' (Site from CRA).	Danyel Johnson (b) (4)	21 Apr 2021 19:46:58
User opened query 'Please add to Con Med Log in Source so data can be verified.' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:41:37
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: MEDICAL GASES, PRODUCT: OXYGEN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 09:00:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	30 Mar 2021 09:00:27
Data point term sent to Coder	System	29 Mar 2021 18:50:08
User entered 'Oxygen'	Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'COPD exacerbation'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0.004'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'mL (mL)'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'as needed (PRN)'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered empty.	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4) (b) (4)	12 Apr 2021 23:15:53
User entered empty.	Danyel Johnson (b) (4) (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '0'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31
	(b) (4)	

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered '08 Oct 2020'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:57:31
User signature succeeded.	Gowdhami Mohan (b) (4)	12 Apr 2021 23:15:53
User entered 'No (N)'	(b) (4) Danyel Johnson (b) (4)	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 10:00:04

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:58:06
User entered empty.	System	29 Mar 2021 18:49:31

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:00:04

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:48:52
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
User entered 'Yes (Y)'	Danyel Johnson (b) (4)	12 Nov 2020 14:43:24

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Chest X-Ray(WNL)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:02

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'COVID 19 Test (negative)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:01
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:44:38

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered '08 Oct 2020'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Influenza A and B testing (Negative)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered 'Adverse Event (AE)'	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:00:04

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:41:05
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:17:35
User entered empty.	Danyel Johnson (b) (4) (b) (4)	12 Nov 2020 14:45:40

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered '14/Oct/2020 09:41'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:00:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:04:07
User entered '13/Nov/2020 14:29'	System	13 Nov 2020 14:29:39

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:00:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:50:19
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:04:04
User entered '1'	(b) (4), (b) (6)	13 Nov 2020 14:29:39

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'USA-US100-2020-MRNA-1273-P301000006'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Serious

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Death

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Yes (Y)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'No (N)'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Gowdhami'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Mohan'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '1655 E. Greenville St'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'Anderson'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered 'SC'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Oct 2020 23:33:50
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:41:38
User entered '29621'	System	14 Oct 2020 13:41:15

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 14:29:25
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 23:33:50
User entered 'US'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 10 Jun 2021 10:00:04

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
	(b) (4)	
User entered '3'	System	10 Feb 2021 15:50:38
User entered '2'	System	13 Nov 2020 14:29:39
User entered '1'	System	14 Oct 2020 13:41:47

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:04

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:46:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '10/Feb/2021 10:50'	(b) (4) System	10 Feb 2021 15:50:38

US3832211

Folder: SAE USA-US100-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:00:04

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:46:26
User signature succeeded.	Gowdhami Mohan (b) (4)	21 Feb 2021 21:35:32
User entered '1'	(b) (4) (b) (4), (b) (6)	10 Feb 2021 15:50:38