

US3202183 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:39:15

All time stamps listed in this document are displayed in GMT

US3202183

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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[Participant ID](#)

US3202183

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

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US3202183

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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

Visit date (dd MMM yyyy)	14 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3202183

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	70
Age Units	YEARS
Age (Derived)	71
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Date of Informed Consent ( <i>dd MMM yyyy</i> )	14 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	HYPERLIPIDEMIA
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)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	GASTROESOPHAGEAL REFLUX DISEASE
Start date (dd MMM yyyy)	UN FEB 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)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN MAR 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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 1988
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1988
Start Year (derived)	1988
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Condition	IRRITABLE BOWEL SYNDROME
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

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

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	14 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:32 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:32
Height ( <i>xxx.x</i> )	158.0 cm
Weight ( <i>xxx.x</i> )	102.0 kg
BMI ( <i>xxx.x</i> )	40.85884 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*) 14 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

If Surgically sterile, date of surgery (*dd MMM yyyy*) UN UNK 1990

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:21

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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

What was the participant's randomization number? 186326

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 10:32
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 AUG 2020
Time of assessment (00:00-23:59)	11:55 (24 HR)
Vital Signs Date and Time (derived)	14 AUG 2020 11:55
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	19 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 11:17 (24 HR)

Treatment Date and Time (derived) 14 AUG 2020 11:17

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 AUG 2020
Collection time (00:00-23:59)	10:50 (24 HR)
Collection date and time (derived)	14 AUG 2020 10:50

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Collection date (dd MMM yyyy)			14 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:47	14 AUG 2020 10:47
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 AUG 2020 11:37

PC Close Date & Time

14 AUG 2020 14:07

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

14 AUG 2020 15:02

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 19:25

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 20:22

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**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

17 AUG 2020 21:01

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 22:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**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):

PC Time Stamp

19 AUG 2020 20:33

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 19:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 AUG 2020 11:37

PC Close Date & Time

14 AUG 2020 14:07

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

14 AUG 2020 15:02

PC Close Date & Time

15 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 19:26

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 20:23

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 21:01

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 22:08

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 20:33

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 19:36

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**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 ☐

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 11:37

PC Close Date & Time

14 AUG 2020 14:07

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**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 ☐

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

14 AUG 2020 15:02

PC Close Date & Time

15 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**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 ☒



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 19:27
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 20:23
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2484

EAB) (1725)

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:02
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	18 AUG 2020 22:09
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 20:34
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

65 of 2484

EAB) (1725)

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 19:37
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3202183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 AUG 2020

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

Comments ATTEMPTS X3 AND LVM

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3202183

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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)	22 SEP 2020
Time of assessment (00:00-23:59)	11:11 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 11:11
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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)	22 SEP 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:22
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3202183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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.*

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 11:35 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 11:35

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

What was the frequency of the study treatment dosing? ONCE

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

US3202183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:31 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:31

US3202183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:29	22 SEP 2020 11:29
Nasopharyngeal Swab 2	No		



US3202183

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 SEP 2020 11:55

PC Close Date & Time

22 SEP 2020 14:25

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.6 °F

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

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

PC Time Stamp	22 SEP 2020 20:48
PC Open Date & Time	22 SEP 2020 15:20
PC Close Date & Time	23 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 17:53

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 19:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:15

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**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):

PC Time Stamp

26 SEP 2020 19:52

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 19:58

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 19:09

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

22 SEP 2020 11:55

PC Close Date & Time

22 SEP 2020 14:25

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**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

22 SEP 2020 20:49

PC Open Date & Time

22 SEP 2020 15:20

PC Close Date & Time

23 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 17:54

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 19:24

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**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

25 SEP 2020 20:15

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

26 SEP 2020 19:52

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

27 SEP 2020 19:58

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

28 SEP 2020 19:09

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**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 ☐

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 11:55

PC Close Date & Time

22 SEP 2020 14:25

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**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 ☐

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 20:50
PC Open Date & Time	22 SEP 2020 15:20
PC Close Date & Time	23 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 17:54
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 3

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 19:25
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:17
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:53
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 19:59
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**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 ☒



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 19:10
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3202183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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*

US3202183

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

---

Was Contact Attempted? Yes ☒ No ☐

---

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

---

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

---

Comments SUBJ DIDN'T ANSWER PHONE  
W 3 ATTEMPTS

---

*If Contact Not Made, please provide Comments*

---

US3202183

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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



US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 OCT 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	20 OCT 2020 11:12
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

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.*

US3202183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

20 OCT 2020

Collection time (00:00-23:59)

11:22 (24 HR)

Collection date and time (derived)

20 OCT 2020 11:22

US3202183

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:10:21

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59



US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

28 OCT 2020 10:28:48

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 21:13:55

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 11:26:29

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

23 NOV 2020 13:46:09

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 15:40:30

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 12:42:21

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 16:57:44

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 12:45:57

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59



US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 11:08:14

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

04 JAN 2021 21:42:24

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 13:50:09

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 09:51:36

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 JAN 2021 22:24:10

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 12:31:07

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 FEB 2021 12:37:12
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 15:37:03

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59



US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 FEB 2021 11:11:15

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 01:17:08

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

07 MAR 2021 07:20:42

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

14 MAR 2021 00:01

---

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

21 MAR 2021 10:07:50

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 MAR 2021 15:48:24

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

04 APR 2021 08:29:52

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 11:42:39

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 APR 2021 12:03:47

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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

26 APR 2021 12:53:42

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

02 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59
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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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03 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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17 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 DEC 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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°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 ☐



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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26 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 DEC 2021 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 537

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

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

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

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

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

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

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 FEB 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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27 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

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**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 APR 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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19 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

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

**US3202183**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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°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 ☐

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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11 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 SEP 2022 23:59

US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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25 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**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 ☐



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

DAY 789

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

Please identify below which symptoms you have experienced or are experiencing (Check all that apply):

Fever (Temperature  $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ ) ☐

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic. I confirm I have read this message and will call the study clinic immediately ☐

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic? No ☐ Yes ☐

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission

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[Patient Cloud Open Date & Time](#)

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09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 OCT 2022 23:59

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US3202183

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
---	--

Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 OCT 2022 23:59

**US3202183**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 15:39:15**

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

US3202183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:44:27

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3202183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 DEC 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LVM FOR DAY 119 PHONE  
CALL.

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	24 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

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) \_\_\_\_\_



US3202183

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

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.*

US3202183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	10:19 (24 HR)
Collection date and time (derived)	24 MAR 2021 10:19

US3202183

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3202183**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

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*

**US3202183**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202183

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:39:15

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"/>



**US3202183**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 15:39:15**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

Visit date (dd MMM yyyy)	13 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 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> )	13 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

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Height	
Weight	
BMI (xxx.x)	

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	13:02 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:02
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Height	
Weight	
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	13:30 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 13:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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.*

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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) 13 JAN 2021

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 13:20

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



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00-23:59)	13:19 (24 HR)
Collection date and time (derived)	13 JAN 2021 13:19

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	13:17
Collection Date and Time (derived)	13 JAN 2021 13:17

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

LEFT A VOICE MESSAGE.  
SUBJECT CALLED BACK

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3202183

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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)	24 FEB 2021
Time of assessment (00:00-23:59)	10:10 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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)	24 FEB 2021
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	24 FEB 2021 10:52
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG



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Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

*Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.*

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Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

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) 24 FEB 2021

What was the treatment time? (00:00-23:59) 10:14 (24 HR)

Treatment Date and Time (derived) 24 FEB 2021 10:14

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

US3202183

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT A VOICE MESSAGE

*If Contact Not Made, please provide Comments*

US3202183

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:26:26

Generated On: 09 Jun 2021 15:39:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202183

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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	OLD57

US3202183

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

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) \_\_\_\_\_

US3202183

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

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.*



US3202183

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 MAR 2021
Collection time (00:00-23:59)	10:19 (24 HR)
Collection date and time (derived)	24 MAR 2021 10:19

US3202183

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Mar 2021 12:56:11

Generated On: 09 Jun 2021 15:39:15

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

AEID	USA-US128-2021-MRNA-1273-P30 1000012
Adverse event	WORSENING OF CERVICAL DEGENERATIVE DISC DISEASE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	1 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	2 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

---

SUBJECT REPORTS  
DEGENERATIVE DISC DISEASE  
HAS BEEN PART OF HER  
MEDICAL HISTORY FOR 20  
YEARS AND HASN'T ACTUALLY  
WORSENEDED SINCE START OF  
STUDY, BUT THE ELECTIVE  
SURGICAL TREATMENT WAS  
POSTPONED DUE TO  
PANDEMIC. THE SURGERY  
REQUIRED AN OVERNIGHT  
STAY IN HOSPITAL FOR  
CERVICAL DISC REPLACEMENT  
AND PER PROTOCOL MUST BE  
ENTERED AS AN SAE DUE TO  
THIS HOSPITALIZATION.  
SUBJECT'S MEDICAL RECORDS  
WERE RECEIVED BUT  
CONSISTED MAINLY OF THE  
PROCEDURE NOTES AS THIS  
WAS A A SURGI-CENTER PART  
OF MEDICAL FACILITY. BASIC  
HEMATOLOGY AND  
CHEMISTRY LABS COLLECTED  
ON 25FEB2021 (-4 DAYS FROM  
SURGERY) WERE INCLUDED IN  
RECORDS. SHE WAS NEGATIVE  
FOR MRSA AND NOT TESTED  
FOR COVID-19 PER RECORDS.  
THE ONLY ABNORMAL  
VALUES ON SAFETY LABS  
WERE NOT NOTED AS  
SIGNIFICANT BY REVIEWING  
INVESTIGATOR. ABNORMALS  
WERE AS FOLLOWS (REF

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

---

RANGES IN PARENTHESIS AND  
UNITS OF VALUE AND REF  
RANGE FOLLOWING  
PARENTHETICAL INFO):  
MPV-11.7 (6.6 -10.6) FL,  
CO2 TOTAL- 32 (22 - 30)  
MMOL/L,  
ANION GAP-9.2 (10.0 - 20.0)  
MMOL/L, GLUCOSE 66 (74 - 106)  
MG/DL; SUBJECT WAS ALSO  
POSITIVE ON PRE-ADMISSION  
LAB FOR MSSA SELECT  
SCREEN BUT THIS DID NOT  
PRECLUDE SURGERY (MRSA  
NEGATIVE) AND WAS NOT  
MENTIONED IN RECORDS AS  
SIGNIFICANT. WILL UPLOAD  
REDACTED RECORDS TO  
SAFETY

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

AEID	
Adverse event	ACUTE POST SURGICAL PAIN IN CERVICAL NECK
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication AMLODIPINE/BENAZEPRIL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 10/20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication BACLOFEN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 10

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	02 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 300

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication MULTI-VITAMIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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 1970	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication TRAZADONE

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 150

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

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Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH SUPPLEMENT

Dose per administration 50

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify MCG

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB	2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication ATORVASTATIN (LIPITOR)

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication CELECOXIB

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GASTROESOPHAGEAL REFLUX  
DISEASE

Dose per administration 20

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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 MAR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
SUPPLEMENT

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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 1970
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication COLESTIPOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPEDEMIA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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)	28 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication VITAMIN B COMPLEX

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB	2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

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Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication OSTEO BI FLEX

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
SUPPLEMENT

Dose per administration 2

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2016
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 FEB	2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication CINNAMON

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
SUPPLEMENT

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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Name of Medication BIOTIN

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH  
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 ☐

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Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:42:37

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	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication MEMANTINE

Prophylaxis Yes ☒  
No ☐

Indication MEMORY SUPPLEMENT

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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	<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"/>

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS- FLU

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication PNEUMONIA 13 VAC

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS- PNEUMONIA

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication TETANUS

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS- TETANUS

Dose per administration 0.5

Dose unit mg ☐  
ug ☐  
mL ☒  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication POST SURGICAL CERVICAL  
NECK PAIN

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication ACUTE POST SURGICAL  
CERVICAL NECK PAIN

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	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)		2 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 25

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN NOV 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

Name of Medication GENERAL ENDOTRACHEAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication WORSENING OF CERVICAL DEGENERATIVE DISC DISEASE

Dose per administration UNK

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify UNKNOWN

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☒  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:42:37

Generated On: 09 Jun 2021 15:39:15

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---



US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 15:26:06

Generated On: 09 Jun 2021 15:39:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
1 MAR 2021	CERVICAL DISC REPLACEMENT	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:39:15

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:39:15

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 ☐

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

SAEID	USA-US128-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

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Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

SAEID	USA-US128-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/MAR/2021 08:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

SAEID	USA-US128-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	16/APR/2021 13:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 17:57:09

Generated On: 09 Jun 2021 15:39:15

SAEID	USA-US128-2021-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	MARK
Investigator's Last Name	MCKENZIE
Site Address: Street	
Site Address: City	
Site Address: State	
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 06:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3202183 (Prod: WR-ClinSearch, LLC)



**US3202183**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 15:39:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:41:02
User entered 'US3202183'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:41

**US3202183**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:21
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:49:56

**US3202183**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:21
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:42

**US3202183**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:21
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:49:56

**US3202183**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'SCRN'	System	14 Aug 2020 14:49:56

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:43
User entered (b) (6) 1949'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:43

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:38:52
User closed query 'please verify, does not match source' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 22:09:30
Query 'please verify, does not match source' answered with 'subject turned 71 the day after Screening Visit/Day 1' (Site from CRA).	Erica Osmundsen (b) (4)	19 Oct 2020 18:00:48
User entered '70' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:00:33
User opened query 'please verify, does not match source' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:24:51
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 15:24:39
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 17:36:23
User entered '71'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'YEARS'	System	02 Sep 2020 21:58:16



**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '71'	System	14 Aug 2020 14:50:09

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:46
User entered 'Female (F)'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:34:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered 'I'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16



**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered empty.	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 15:39:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

US3202183

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:39:15

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:36:32
User entered '0'	Erica Osmundsen (b) (4)	02 Sep 2020 21:58:16

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Aug 2020'	System	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09



US3202183

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:15

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:09

US3202183

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:39:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:56:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:09:42

**US3202183**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 15:39:15**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'I'	System	14 Aug 2020 14:50:15

US3202183

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:39:15

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 17:57:10
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 14:50:15

US3202183

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:39:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User closed query 'Please verify and update EDC to match source, source = Seasonal Allergies, Sleep Apnea, IBS ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 22:10:06
Query 'Please verify and update EDC to match source, source = Seasonal Allergies, Sleep Apnea, IBS ' answered with 'DONE' (Site from CRA).	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:02
User opened query 'Please verify and update EDC to match source, source = Seasonal Allergies, Sleep Apnea, IBS ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:42:07
Query 'please update EDC to match source, source = seasonal allergies, sleep apnea, and IBS' canceled (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:40:31
User opened query 'please update EDC to match source, source = seasonal allergies, sleep apnea, and IBS' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:40:15
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:37:23
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 13:37:17
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:06:37
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:22:35



US3202183

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:50:58
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'MENORRHAGIA ADDED' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:21
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 07:42:46
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:24:45
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 01:44:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 01:44:41
Data point term sent to Coder	System	19 Sep 2020 01:43:39
User entered 'hysterectomy'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

US3202183

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:47
User entered 'un UNK 1990'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

US3202183

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:48
User entered '0'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

**US3202183**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:50
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

US3202183

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:52
User entered 'un UNK 1990'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

US3202183

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:53
User entered '0'	Erica Osmundsen (b) (4)	19 Sep 2020 01:42:57

**US3202183**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1990'	System	19 Sep 2020 01:42:57

**US3202183**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1990'	System	19 Sep 2020 01:42:57



**US3202183**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1990'	System	19 Sep 2020 01:42:57

**US3202183**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1990'	System	19 Sep 2020 01:42:57

US3202183

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:07
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 13:10:56
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 13:10:56
Data point term sent to Coder	System	23 Sep 2020 13:09:37
User entered 'Hypertension'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:09
User entered 'UN UNK 1975'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:11
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:12
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:14
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:24:16
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:08:57



**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1975'	System	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1975'	System	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:08:57

**US3202183**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:08:57

US3202183

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:02
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) (b) (4)	23 Sep 2020 13:10:56
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 13:10:56
Data point term sent to Coder	System	23 Sep 2020 13:09:38
User entered 'Osteoarthritis'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:04
User entered 'UN UNK 1970'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29

US3202183

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:39:15

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:05
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:08
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29



**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:10
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:23:12
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1970'	System	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1970'	System	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:09:29

**US3202183**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:09:29

US3202183

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:21:05
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 13:11:51
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 13:11:51
Data point term sent to Coder	System	23 Sep 2020 13:10:39
User entered 'Depression'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24

US3202183

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:01:04
User closed query 'please verify, one source =2018 and another = 2020' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 14:10:36
Query 'please verify, one source =2018 and another = 2020' answered with 'CONFIRMED --2018 PER PATIENT CLARIFICATION' (Site from CRA).	Erica Osmundsen (b) (4)	19 Oct 2020 18:20:58
User opened query 'please verify, one source =2018 and another = 2020' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:22:17
User entered 'UN UNK 2018'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24



**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:21:06
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:21:08
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:21:10
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24

US3202183

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:21:14
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2018'	System	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2018'	System	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:10:24

**US3202183**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:10:24



US3202183

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 13:13:00
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 13:13:00
Data point term sent to Coder	System	23 Sep 2020 13:11:40
User entered 'Hyperlipidemia'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:15
User entered 'UN UNK 2017'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

US3202183

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:17
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:19
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:20
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:29:23
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2017'	System	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2017'	System	23 Sep 2020 13:10:48



**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:10:48

**US3202183**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:10:48

US3202183

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:39:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:31:57
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Sep 2020 13:13:01
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 13:13:01
Data point term sent to Coder	System	23 Sep 2020 13:12:41
User entered 'Gastroesophageal reflux disease'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:12:09

US3202183

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:58:33
User closed query 'Per Medical History form, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:39:47
Query 'Per Medical History form, this is discrepant. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	21 Nov 2020 15:07:21
User entered 'UN Feb 2020' reason for change: Data Entry Error	zackery harmon (b) (4)	21 Nov 2020 15:07:17
User opened query 'Per Medical History form, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 18:02:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 18:01:49
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 13:32:07
User entered 'UN Mar 2020'	Tiffany Jewell (b) (4)	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:32:09
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:32:12
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:33:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:33:08
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:12:09



**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Feb 2020'	System	21 Nov 2020 15:07:17
User entered 'Mar 2020'	System	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:12:09

**US3202183**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	23 Sep 2020 13:12:09

US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:17:23
Data point term sent to Coder	System	19 Oct 2020 18:16:57
User entered 'SEASONAL ALLERGIES'	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31

US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:44
User entered 'UN Mar 2020'	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31

US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:46
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31

US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:48
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31



US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:51
User entered empty.	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31

US3202183

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:03:52
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:16:31

**US3202183**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Mar 2020'	System	19 Oct 2020 18:16:31

**US3202183**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	19 Oct 2020 18:16:31

**US3202183**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:16:31

**US3202183**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:16:31

US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:04
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:23:47
Data point term sent to Coder	System	19 Oct 2020 18:23:12
Coding entries removed.	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:04
User entered 'MENORRHAGIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Gastroesophageal reflux disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:20:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:20:42
Data point term sent to Coder	System	19 Oct 2020 18:19:03
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57

US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:06
User entered 'UN UNK 1988' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:04
User entered 'UN Feb 2020'	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57



US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:08
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57

US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:10
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:04
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57

US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:13
User entered 'UN UNK 1990' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:23:04
User entered empty.	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57

US3202183

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:14
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:18:57

**US3202183**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1988'	System	19 Oct 2020 18:23:04
User entered 'Feb 2020'	System	19 Oct 2020 18:18:57

**US3202183**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1988'	System	19 Oct 2020 18:23:04
User entered '2020'	System	19 Oct 2020 18:18:57

**US3202183**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1990'	System	19 Oct 2020 18:23:04
User entered empty.	System	19 Oct 2020 18:18:57

**US3202183**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1990'	System	19 Oct 2020 18:23:04
User entered empty.	System	19 Oct 2020 18:18:57



US3202183

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:27
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)	19 Oct 2020 18:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:25:37
Data point term sent to Coder	System	19 Oct 2020 18:24:14
User entered 'SLEEP APNEA'	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

**US3202183**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:29
User entered 'UN UNK 1970'	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

US3202183

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:30
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

US3202183

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:39:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:34
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

US3202183

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:39:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:36
User entered empty.	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

US3202183

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:38
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:24:09

**US3202183**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 1970'	System	19 Oct 2020 18:24:09

**US3202183**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '1970'	System	19 Oct 2020 18:24:09



**US3202183**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:24:09

**US3202183**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:24:09

US3202183

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:56
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:40:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:40:28
Data point term sent to Coder	System	19 Oct 2020 18:38:52
User entered 'IRRITABLE BOWEL SYNDROME'	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23

**US3202183**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:57
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23

US3202183

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:05:59
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23

US3202183

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:06:01
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23

US3202183

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:15

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:06:05
User entered empty.	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23

US3202183

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:39:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 18:06:03
User entered '0'	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:23



**US3202183**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2019'	System	19 Oct 2020 18:38:23

**US3202183**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2019'	System	19 Oct 2020 18:38:23

**US3202183**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:38:23

**US3202183**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	19 Oct 2020 18:38:23

US3202183

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:21
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Degenerative disc disease - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:44:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:44:36
Data point term sent to Coder	System	24 Mar 2021 15:27:39
User entered 'degenerative disc disease'	Teresa Deese (b) (4)	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:23
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'UN UNK 2020'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:25
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:26
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:26:55



**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:30
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:32
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2020'	System	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:26:55

**US3202183**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:26:55

US3202183

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:37
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:28:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 15:28:46
Data point term sent to Coder	System	24 Mar 2021 15:27:41
User entered 'scoliosis'	Teresa Deese (b) (4)	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:42
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'UN UNK 2020'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:18



**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:44
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:18

US3202183

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:39:15

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:47
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:49
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered empty.	(b) (4)	24 Mar 2021 15:27:18
	Teresa Deese (b) (4)	

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:51
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2020'	System	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:27:18

**US3202183**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:27:18



US3202183

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:39:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:57
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Lumbar spinal cord and nerve root disorders, PT: Sciatica, LLT: Sciatica - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	24 Mar 2021 15:44:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 15:44:35
Data point term sent to Coder	System	24 Mar 2021 15:27:41
User entered 'sciatica'	Teresa Deese (b) (4) (b) (4) (b) (4)	24 Mar 2021 15:27:35

US3202183

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:39:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:50:59
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'UN UNK 2020'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:51:01
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:51:03
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:51:05
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:51:07
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'Jan 2020'	System	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '2020'	System	24 Mar 2021 15:27:35



**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered empty.	System	24 Mar 2021 15:27:35

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered '10:32'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered '14 Aug 2020 10:32'	System	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered '158.0' cm	zackery harmon (b) (4)	06 Sep 2020 15:31:05
DataPoint set to visible.	(b) (4) System	14 Aug 2020 14:50:15

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered '102.0' kg	zackery harmon (b) (4)	06 Sep 2020 15:31:05
DataPoint set to visible.	(b) (4) System	14 Aug 2020 14:50:15



US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User closed query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 10:27:35
Query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' answered with 'unable to update randomization data in IRT DEVIATION ACKNOWLEDGED AND NOTED CORRECT GROUP IN SOURCE AS 65+ W/ HEALTH RISK' (Site from DM).	Erica Osmundsen (b) (4)	15 Apr 2021 19:02:01
User opened query 'Per CDM: per sponsor review, BMI $\geq$ 40 kg/m2 yet Severe obesity = No in Randomization Form. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 05:17:57
User entered '40.85884'	System	06 Sep 2020 15:31:05
DataPoint set to visible.	System	14 Aug 2020 14:50:15

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'kg/m2'	System	06 Sep 2020 15:31:05
DataPoint set to visible.	System	14 Aug 2020 14:50:15

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'bpm'	System	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05



US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'breaths/min'	System	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'mmHg'	System	06 Sep 2020 15:31:05

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:22
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User entered 'mmHg'	System	06 Sep 2020 15:31:05

**US3202183**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43

US3202183

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43

US3202183

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:45
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:22:51



US3202183

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:14:45
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:22:51

US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:15:54
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:15:56
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 08:20:39
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' answered with 'ADDED INFORMATION' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 18:39:15
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile and HYSTERECTOMY is recorded in MH; however associated condition with this surgery is not recorded as an MH condition. Ensure associated condition is recorded. Review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 17:28:35
User closed query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:04:53
Query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' answered with 'entered' (Site from DM).	Erica Osmundsen (b) (4)	19 Sep 2020 03:36:49
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:15:58
User opened query 'Per CDM: 'Surgically Sterile' is recorded but there is no record of this on the Medical History form. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Sep 2020 06:46:57
User entered 'Surgically sterile (SURGICALLY STERILE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:01
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

**US3202183**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:39:15**

**If Surgically sterile, date of surgery (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:04
User entered 'un UNK 1990'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

**US3202183**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 15:39:15**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:17
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34



US3202183

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:39:15

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:16:19
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:23:34

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31



US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

**US3202183**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 15:39:15**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User entered '0'	(b) (4) zackery harmon (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**Resides in Nursing Home or Assisted Living Facility**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31



US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

**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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

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)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered '0'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User entered 'I'	(b) (4) zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:39:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 09:34:43
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:15
User entered 'Plans on routinely going to places where people gather'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:31

US3202183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:58
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:42

US3202183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:58
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:42



US3202183

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:22:58
User entered 'Clinic (Clinic)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:24:42

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'VISIT1'	System	06 Sep 2020 15:24:42

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered '14 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:44:27

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:28:37
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:28:37
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	14 Aug 2020 14:44:27
User entered '186326' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:44:27

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	14 Aug 2020 14:44:27

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User closed query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 21:48:30
Query ' PER CDM: Please complete this section of the form' answered with 'fields fixed' (Site from DM).	zackery harmon (b) (4)	04 Sep 2020 11:58:10
User entered 'No (N)'	(b) (4) zackery harmon (b) (4)	04 Sep 2020 11:58:07
User opened query ' PER CDM: Please complete this section of the form' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 17:21:40

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	04 Sep 2020 11:58:07

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:29:43
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 15:29:17
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	04 Sep 2020 11:58:07



US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	04 Sep 2020 11:58:07

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:34:20
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	04 Sep 2020 11:58:07

US3202183

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:39:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:28:33
User entered 'No (N)'	Tiffany Jewell (b) (4)	22 Sep 2020 17:03:07
Amendment Manager: DataPoint set to visible.	(b) (4)	System
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 10:20:48 19 Sep 2020 07:15:06

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Pre-Dose (PREDOSE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23



US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '10:32'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '14 Aug 2020 10:32'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '36.4' C	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '80'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23



US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'bpm'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '20'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'breaths/min'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '138'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '74'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23



US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered missing code ND - Not Done.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Post-Dose (POSTDOSE)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '11:55'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '14 Aug 2020 11:55'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '36.8' C	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered 'Oral (Oral)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23



US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '71'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'bpm'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '19'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'breaths/min'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '135'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:38:49
User entered '89'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:30:23



US3202183

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	06 Sep 2020 15:30:23

US3202183

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:39:34
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:22:22

US3202183

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:39:34
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:22:22

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'MRNA-1273 OR PLACEBO'	System	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered '14 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09



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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered '11:17'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '14 Aug 2020 11:17'	System	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	17 Sep 2020 18:40:27
User entered 'ONCE'	System	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'INTRAMUSCULAR'	System	14 Aug 2020 15:34:09

US3202183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:46
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:28:52

US3202183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:46
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:28:52

US3202183

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:46
User entered '10:50'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:28:52



**US3202183**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '14 Aug 2020 10:50'	System	06 Sep 2020 15:28:52

US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:56
User entered '14 Aug 2020'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:56
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:56
User entered '10:47'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '14 Aug 2020 10:47'	System	06 Sep 2020 15:29:05

US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:56
User entered 'No (N)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05



US3202183

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:41:56
User entered empty.	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:05

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered empty.	System	06 Sep 2020 15:29:05

US3202183

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Sep 2020 18:42:10
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	06 Sep 2020 15:29:10

**US3202183**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	06 Sep 2020 15:29:10

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 11:37'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 14:07'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 15:02'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 2'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0f27f3bd-df4c-41d3-9b4d-6e058274b67a'	System	15 Aug 2020 23:25:40
User entered 'Yes (Y)'	System	15 Aug 2020 23:25:40



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0f27f3bd-df4c-41d3-9b4d-6e058274b67a'	System	15 Aug 2020 23:25:40
User entered '97.2'	System	15 Aug 2020 23:25:40

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0f27f3bd-df4c-41d3-9b4d-6e058274b67a'	System	15 Aug 2020 23:25:40
User entered 'No (N)'	System	15 Aug 2020 23:25:40

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0f27f3bd-df4c-41d3-9b4d-6e058274b67a'	System	15 Aug 2020 23:25:40
User entered '15 Aug 2020 19:25'	System	15 Aug 2020 23:25:40

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 3'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cadcb50c-e902-469b-b3a1-9e62f54deaea'	System	17 Aug 2020 00:22:39
User entered 'Yes (Y)'	System	17 Aug 2020 00:22:39

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cadcb50c-e902-469b-b3a1-9e62f54deaea'	System	17 Aug 2020 00:22:39
User entered '97.6'	System	17 Aug 2020 00:22:39



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cadcb50c-e902-469b-b3a1-9e62f54deaea'	System	17 Aug 2020 00:22:39
User entered 'No (N)'	System	17 Aug 2020 00:22:39

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cadcb50c-e902-469b-b3a1-9e62f54deaea'	System	17 Aug 2020 00:22:39
User entered '16 Aug 2020 20:22'	System	17 Aug 2020 00:22:39

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 4'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:00:51', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a8a24e47-b71f-4149-a345-772d61c371d0'	System	18 Aug 2020 01:01:15
User entered 'Yes (Y)'	System	18 Aug 2020 01:01:15

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:00:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a8a24e47-b71f-4149-a345-772d61c371d0'	System	18 Aug 2020 01:01:15
User entered '98.1'	System	18 Aug 2020 01:01:15

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a8a24e47-b71f-4149-a345-772d61c371d0'	System	18 Aug 2020 01:01:15
User entered 'No (N)'	System	18 Aug 2020 01:01:15



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:11', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a8a24e47-b71f-4149-a345-772d61c371d0'	System	18 Aug 2020 01:01:15
User entered '17 Aug 2020 21:01'	System	18 Aug 2020 01:01:15

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 5'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0e8af5b8-237f-4604-bea7-7d6d690f3c4e'	System	19 Aug 2020 02:08:36
User entered 'Yes (Y)'	System	19 Aug 2020 02:08:36

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0e8af5b8-237f-4604-bea7-7d6d690f3c4e' User entered '97.8'	System	19 Aug 2020 02:08:36
	System	19 Aug 2020 02:08:36

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:26', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0e8af5b8-237f-4604-bea7-7d6d690f3c4e'	System	19 Aug 2020 02:08:36
User entered 'No (N)'	System	19 Aug 2020 02:08:36

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '0e8af5b8-237f-4604-bea7-7d6d690f3c4e'	System	19 Aug 2020 02:08:36
User entered '18 Aug 2020 22:08'	System	19 Aug 2020 02:08:36



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 6'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:32:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a1a713b0-f5c1-4a28-b5b9-77ded78f2afe'	System	20 Aug 2020 00:33:10
User entered 'Yes (Y)'	System	20 Aug 2020 00:33:10

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:32:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a1a713b0-f5c1-4a28-b5b9-77ded78f2afe'	System	20 Aug 2020 00:33:10
User entered '98.2'	System	20 Aug 2020 00:33:10

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a1a713b0-f5c1-4a28-b5b9-77ded78f2afe'	System	20 Aug 2020 00:33:10
User entered 'No (N)'	System	20 Aug 2020 00:33:10

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:07', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'a1a713b0-f5c1-4a28-b5b9-77ded78f2afe'	System	20 Aug 2020 00:33:10
User entered '19 Aug 2020 20:33'	System	20 Aug 2020 00:33:10

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:34:09



US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 7'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:35:49', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '6b75a2e1-65cb-4afe-ba69-67523c301c2b'	System	20 Aug 2020 23:36:08
User entered 'Yes (Y)'	System	20 Aug 2020 23:36:08

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:35:57', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '6b75a2e1-65cb-4afe-ba69-67523c301c2b'	System	20 Aug 2020 23:36:08
User entered '97.2'	System	20 Aug 2020 23:36:08

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '6b75a2e1-65cb-4afe-ba69-67523c301c2b'	System	20 Aug 2020 23:36:08
User entered 'No (N)'	System	20 Aug 2020 23:36:08

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:06', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '6b75a2e1-65cb-4afe-ba69-67523c301c2b'	System	20 Aug 2020 23:36:08
User entered '20 Aug 2020 19:36'	System	20 Aug 2020 23:36:08

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:34:09



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 11:37'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 14:07'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 15:02'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 2'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '77ece1de-9199-43a6-bb31-32fa15a25c6e'	System	15 Aug 2020 23:26:13
User entered 'None (1)'	System	15 Aug 2020 23:26:13

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:54', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '77ece1de-9199-43a6-bb31-32fa15a25c6e'	System	15 Aug 2020 23:26:13
User entered 'No (N)'	System	15 Aug 2020 23:26:13

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:25:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '77ece1de-9199-43a6-bb31-32fa15a25c6e'	System	15 Aug 2020 23:26:13
User entered 'No (N)'	System	15 Aug 2020 23:26:13



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '77ece1de-9199-43a6-bb31-32fa15a25c6e'	System	15 Aug 2020 23:26:13
User entered 'None (1)'	System	15 Aug 2020 23:26:13

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:11', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '77ece1de-9199-43a6-bb31-32fa15a25c6e'	System	15 Aug 2020 23:26:13
User entered '15 Aug 2020 19:26'	System	15 Aug 2020 23:26:13

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 3'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '93ea3b0e-28bc-4ec5-a984-68119cc2057b'	System	17 Aug 2020 00:23:10
User entered 'None (1)'	System	17 Aug 2020 00:23:10

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:49', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '93ea3b0e-28bc-4ec5-a984-68119cc2057b'	System	17 Aug 2020 00:23:10
User entered 'No (N)'	System	17 Aug 2020 00:23:10

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:22:54', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '93ea3b0e-28bc-4ec5-a984-68119cc2057b'	System	17 Aug 2020 00:23:10
User entered 'No (N)'	System	17 Aug 2020 00:23:10



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '93ea3b0e-28bc-4ec5-a984-68119cc2057b'	System	17 Aug 2020 00:23:10
User entered 'None (1)'	System	17 Aug 2020 00:23:10

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:06', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '93ea3b0e-28bc-4ec5-a984-68119cc2057b'	System	17 Aug 2020 00:23:10
User entered '16 Aug 2020 20:23'	System	17 Aug 2020 00:23:10

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 4'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4f26cb01-b1ef-4b4f-b193-3274422efcc9'	System	18 Aug 2020 01:01:41
User entered 'None (1)'	System	18 Aug 2020 01:01:41

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4f26cb01-b1ef-4b4f-b193-3274422efcc9'	System	18 Aug 2020 01:01:41
User entered 'No (N)'	System	18 Aug 2020 01:01:41

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:26', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4f26cb01-b1ef-4b4f-b193-3274422efcc9'	System	18 Aug 2020 01:01:41
User entered 'No (N)'	System	18 Aug 2020 01:01:41



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:34', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4f26cb01-b1ef-4b4f-b193-3274422efcc9'	System	18 Aug 2020 01:01:41
User entered 'None (1)'	System	18 Aug 2020 01:01:41

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4f26cb01-b1ef-4b4f-b193-3274422efcc9'	System	18 Aug 2020 01:01:41
User entered '17 Aug 2020 21:01'	System	18 Aug 2020 01:01:41

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 5'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '97f7f153-f251-4a5b-bf64-544a42a6a693'	System	19 Aug 2020 02:08:57
User entered 'None (1)'	System	19 Aug 2020 02:08:57

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '97f7f153-f251-4a5b-bf64-544a42a6a693'	System	19 Aug 2020 02:08:57
User entered 'No (N)'	System	19 Aug 2020 02:08:57

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:46', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '97f7f153-f251-4a5b-bf64-544a42a6a693'	System	19 Aug 2020 02:08:57
User entered 'No (N)'	System	19 Aug 2020 02:08:57



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:52', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '97f7f153-f251-4a5b-bf64-544a42a6a693'	System	19 Aug 2020 02:08:57
User entered 'None (1)'	System	19 Aug 2020 02:08:57

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:08:55', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '97f7f153-f251-4a5b-bf64-544a42a6a693'	System	19 Aug 2020 02:08:57
User entered '18 Aug 2020 22:08'	System	19 Aug 2020 02:08:57

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 6'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:13', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '679bbe5a-f9ee-4e30-bd90-90b3a569d58a'	System	20 Aug 2020 00:33:38
User entered 'None (1)'	System	20 Aug 2020 00:33:38

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:17', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '679bbe5a-f9ee-4e30-bd90-90b3a569d58a'	System	20 Aug 2020 00:33:38
User entered 'No (N)'	System	20 Aug 2020 00:33:38

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '679bbe5a-f9ee-4e30-bd90-90b3a569d58a'	System	20 Aug 2020 00:33:38
User entered 'No (N)'	System	20 Aug 2020 00:33:38



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:31', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '679bbe5a-f9ee-4e30-bd90-90b3a569d58a'	System	20 Aug 2020 00:33:38
User entered 'None (1)'	System	20 Aug 2020 00:33:38

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:35', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '679bbe5a-f9ee-4e30-bd90-90b3a569d58a'	System	20 Aug 2020 00:33:38
User entered '19 Aug 2020 20:33'	System	20 Aug 2020 00:33:38

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 7'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:15', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'dbb735e6-a738-485a-8a07-bf05dc2a9f63'	System	20 Aug 2020 23:36:35
User entered 'None (1)'	System	20 Aug 2020 23:36:35

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:19', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'dbb735e6-a738-485a-8a07-bf05dc2a9f63'	System	20 Aug 2020 23:36:35
User entered 'No (N)'	System	20 Aug 2020 23:36:35

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'dbb735e6-a738-485a-8a07-bf05dc2a9f63'	System	20 Aug 2020 23:36:35
User entered 'No (N)'	System	20 Aug 2020 23:36:35



US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'dbb735e6-a738-485a-8a07-bf05dc2a9f63'	System	20 Aug 2020 23:36:35
User entered 'None (1)'	System	20 Aug 2020 23:36:35

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:31', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'dbb735e6-a738-485a-8a07-bf05dc2a9f63'	System	20 Aug 2020 23:36:35
User entered '20 Aug 2020 19:36'	System	20 Aug 2020 23:36:35

US3202183

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 11:37'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 14:07'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 1, after vaccination (at home)'	System	14 Aug 2020 15:34:09



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '14 Aug 2020 15:02'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 2'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:23', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:31', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:43', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:26:51', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:27:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'None (0)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:27:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered 'No (N)'	System	15 Aug 2020 23:27:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-15T19:27:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ba0a48a6-03e3-4a3b-acab-c8ba884cc00f'	System	15 Aug 2020 23:27:29
User entered '15 Aug 2020 19:27'	System	15 Aug 2020 23:27:29

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '15 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 3'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:16', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:20', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'None (0)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered 'No (N)'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-16T20:23:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c538837-6f7b-4be1-9f93-c140346a72ee'	System	17 Aug 2020 00:23:49
User entered '16 Aug 2020 20:23'	System	17 Aug 2020 00:23:49

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '16 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 11:59'	System	14 Aug 2020 15:34:09



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 4'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:46', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:01:57', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:02:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'None (0)'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:02:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered 'No (N)'	System	18 Aug 2020 01:02:11



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-17T21:02:08', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '7bb1d8be-d97a-4eb5-9ccd-6c72e97c4172'	System	18 Aug 2020 01:02:11
User entered '17 Aug 2020 21:02'	System	18 Aug 2020 01:02:11

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '17 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 5'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:13', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:17', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:20', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'None (0)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered 'No (N)'	System	19 Aug 2020 02:09:29

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-18T22:09:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'bdf3d7e2-294a-4c93-9d65-35a680af0ab3'	System	19 Aug 2020 02:09:29
User entered '18 Aug 2020 22:09'	System	19 Aug 2020 02:09:29

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '18 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 6'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:41', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:44', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:47', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:33:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'None (0)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:34:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered 'No (N)'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-19T20:34:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '64fb365b-5ad8-434c-9cdf-71783bea1b7f'	System	20 Aug 2020 00:34:06
User entered '19 Aug 2020 20:34'	System	20 Aug 2020 00:34:06

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '19 Aug 2020 12:00'	System	14 Aug 2020 15:34:09



**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 7'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:39', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:43', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:46', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'None (0)'	System	20 Aug 2020 23:37:02



US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:36:57', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered 'No (N)'	System	20 Aug 2020 23:37:02

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-08-20T19:37:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '638dba8c-1e31-4d9c-8a60-ff2ea2936658'	System	20 Aug 2020 23:37:02
User entered '20 Aug 2020 19:37'	System	20 Aug 2020 23:37:02

**US3202183**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '20 Aug 2020 12:00'	System	14 Aug 2020 15:34:09

US3202183

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '21 Aug 2020 11:59'	System	14 Aug 2020 15:34:09

US3202183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:23
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:15:02

US3202183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:09:52
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:53:42
Query 'Safety Call day 8 was made on 26AUG2020 +2day OOW Call should have occurred on 24AUG2020 a Protocol Deviation is needed for this Safety Call ' canceled (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:53:40
User opened query 'Safety Call day 8 was made on 26AUG2020 +2day OOW Call should have occurred on 24AUG2020 a Protocol Deviation is needed for this Safety Call ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 13:54:18
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'The date is correct' (Site from System).	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:15:34
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	23 Sep 2020 13:15:02
User entered '26 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:15:02

US3202183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:28
User entered 'Contact Made (CONTACT MADE)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:15:02

US3202183

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 13:50:31
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:15:02



US3202183

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:59:30
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Sep 2020 15:31:57

**US3202183**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	22 Sep 2020 15:31:57

US3202183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:51:08
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	14 Nov 2020 12:47:43
User closed query 'please provide source documentation for call not done.' (Site from CRA).	(b) (4)	
Query 'please provide source documentation for call not done.' answered with 'calls for day 8 and day 22 made close together so middle call not done' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 22:09:12
	Erica Osmundsen (b) (4)	16 Oct 2020 23:46:03
User opened query 'please provide source documentation for call not done.' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 16:09:08
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 16:08:42
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:59:02
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:17:12
	(b) (4)	

US3202183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:51:08
DataPoint Un-verified.	zackery harmon (b) (4)	14 Nov 2020 12:47:43
User entered '30 Aug 2020' reason for change: Data Entry Error	(b) (4)	14 Nov 2020 12:47:43
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:59:02
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 13:17:12

US3202183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:51:08
DataPoint Un-verified.	zackery harmon (b) (4)	14 Nov 2020 12:47:43
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	14 Nov 2020 12:47:43
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 15:59:02
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 13:17:12

US3202183

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:51:08
DataPoint Un-verified.	zackery harmon (b) (4)	14 Nov 2020 12:47:43
User entered 'attempts x3 and LVM' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	14 Nov 2020 12:47:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:59:02
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:17:12

US3202183

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 15:59:20
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Sep 2020 15:32:03

**US3202183**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	22 Sep 2020 15:32:03



**US3202183**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:09:42
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:16:33

**US3202183**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 16:09:42
User entered '4 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:16:33

US3202183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:56:47
User closed query 'Per Safety 3 following Dose 1 source, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:39:22
Query 'Per Safety 3 following Dose 1 source, this is discrepant. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	21 Nov 2020 15:09:03
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4)	21 Nov 2020 15:08:36
User opened query 'Per Safety 3 following Dose 1 source, this is discrepant. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:14:15
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:20
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:09:42
User entered 'Contact Not Made (CONTACT NOT MADE)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:16:33

US3202183

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 16:56:52
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	21 Nov 2020 15:08:36
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:13:24
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 16:09:42
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	23 Sep 2020 13:16:43
User entered 'No answer' reason for change: Data Entry Error	Tiffany Jewell (b) (4)	23 Sep 2020 13:16:43
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	23 Sep 2020 13:16:33
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 13:16:33

US3202183

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:17:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Sep 2020 15:32:09

**US3202183**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	22 Sep 2020 15:32:09

US3202183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:33
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:18

US3202183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:33
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 11:37:57
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'The date is correct' (Site from System).	Tiffany Jewell (b) (4)	22 Sep 2020 17:03:26
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Sep 2020 17:03:18
User entered '22 Sep 2020'	Tiffany Jewell (b) (4)	22 Sep 2020 17:03:18



US3202183

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 18:36:33
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:18

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'VISIT2'	System	22 Sep 2020 17:03:18

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '22 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '11:11'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '22 Sep 2020 11:11'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '97.2' F	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22



US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '73'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'bpm'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'breaths/min'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '129'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	23 Sep 2020 13:19:22



US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '84'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '22 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '12:22'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '22 Sep 2020 12:22'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '36.1' C	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22



US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '66'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'bpm'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'breaths/min'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '114'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	23 Sep 2020 13:19:22



US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:10:18
User entered '77'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	23 Sep 2020 13:19:22

US3202183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:19
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:34

US3202183

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:19
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:34

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered empty.	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered empty.	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 15:42:17



US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User closed query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM). Query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. answered with 'OOW-Scheduling conflict between site and subject' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User opened query 'Per CDM: Visit date noted is out of window, however AE page need to be updated for dose delay and interruptions. Please review and update accordingly else clarify''. (Site from DM). User entered '22 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	07 Oct 2020 13:47:02
	(b) (4), (b) (6)	05 Oct 2020 17:15:24
	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered '11:35'	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '22 Sep 2020 11:35'	System	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered 'Left Arm (LEFT ARM)'	Erica Osmundsen (b) (4)	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:11:39
User entered 'ONCE'	System	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 15:42:17

US3202183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:57
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:55

US3202183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:57
User entered '22 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:55



US3202183

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:11:57
User entered '11:31'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:03:55

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '22 Sep 2020 11:31'	System	22 Sep 2020 17:03:55

US3202183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:39:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:05
User entered '22 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:06

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	22 Sep 2020 17:04:06

US3202183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:05
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:06

US3202183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:39:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:05
User entered '11:29'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:06

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '22 Sep 2020 11:29'	System	22 Sep 2020 17:04:06

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	22 Sep 2020 17:04:06



US3202183

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:05
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:06

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:39:15**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:05
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:06

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered empty.	System	22 Sep 2020 17:04:06

US3202183

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:11
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	22 Sep 2020 17:04:12

**US3202183**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	22 Sep 2020 17:04:12

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 11:55'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 14:25'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:48:33', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f49cbccd-6001-4d11-b013-b0d5656ab22e'	System	23 Sep 2020 00:49:04
User entered 'Yes (Y)'	System	23 Sep 2020 00:49:04



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:48:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f49cbccd-6001-4d11-b013-b0d5656ab22e'	System	23 Sep 2020 00:49:04
User entered '97.6'	System	23 Sep 2020 00:49:04

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:48:51', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f49cbccd-6001-4d11-b013-b0d5656ab22e'	System	23 Sep 2020 00:49:04
User entered 'No (N)'	System	23 Sep 2020 00:49:04

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:48:58', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f49cbccd-6001-4d11-b013-b0d5656ab22e'	System	23 Sep 2020 00:49:04
User entered '22 Sep 2020 20:48'	System	23 Sep 2020 00:49:04

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 15:20'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 2'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'e04a206f-b82a-4a4e-bc0c-55c7fbd0969f'	System	23 Sep 2020 21:53:48
User entered 'Yes (Y)'	System	23 Sep 2020 21:53:48

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:33', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'e04a206f-b82a-4a4e-bc0c-55c7fbd0969f' User entered '97.8'	System	23 Sep 2020 21:53:48



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'e04a206f-b82a-4a4e-bc0c-55c7fbd0969f'	System	23 Sep 2020 21:53:48
User entered 'No (N)'	System	23 Sep 2020 21:53:48

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:43', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'e04a206f-b82a-4a4e-bc0c-55c7fbd0969f' User entered '23 Sep 2020 17:53'	System	23 Sep 2020 21:53:48
	System	23 Sep 2020 21:53:48

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 3'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4ca101b7-7e90-4f6d-bde3-a7d9e503b484'	System	24 Sep 2020 23:24:30
User entered 'Yes (Y)'	System	24 Sep 2020 23:24:30

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4ca101b7-7e90-4f6d-bde3-a7d9e503b484'	System	24 Sep 2020 23:24:30
User entered '98.2'	System	24 Sep 2020 23:24:30

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:17', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4ca101b7-7e90-4f6d-bde3-a7d9e503b484'	System	24 Sep 2020 23:24:30
User entered 'No (N)'	System	24 Sep 2020 23:24:30



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '4ca101b7-7e90-4f6d-bde3-a7d9e503b484'	System	24 Sep 2020 23:24:30
User entered '24 Sep 2020 19:24'	System	24 Sep 2020 23:24:30

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 4'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:16', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c58660a-ae40-4616-9188-50761927757f'	System	26 Sep 2020 00:15:37
User entered 'Yes (Y)'	System	26 Sep 2020 00:15:37

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c58660a-ae40-4616-9188-50761927757f' User entered '97.6'	System	26 Sep 2020 00:15:37

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c58660a-ae40-4616-9188-50761927757f'	System	26 Sep 2020 00:15:37
User entered 'No (N)'	System	26 Sep 2020 00:15:37

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c58660a-ae40-4616-9188-50761927757f' User entered '25 Sep 2020 20:15'	System	26 Sep 2020 00:15:37



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 5'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '598b3491-5497-409d-b5d4-fc830f929038'	System	26 Sep 2020 23:52:24
User entered 'Yes (Y)'	System	26 Sep 2020 23:52:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '598b3491-5497-409d-b5d4-fc830f929038'	System	26 Sep 2020 23:52:24
User entered '98.1'	System	26 Sep 2020 23:52:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:15', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '598b3491-5497-409d-b5d4-fc830f929038'	System	26 Sep 2020 23:52:24
User entered 'No (N)'	System	26 Sep 2020 23:52:24

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '598b3491-5497-409d-b5d4-fc830f929038'	System	26 Sep 2020 23:52:24
User entered '26 Sep 2020 19:52'	System	26 Sep 2020 23:52:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 6'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:57:31', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '481113f5-1648-495d-8a32-a1b97ba8d2e5'	System	27 Sep 2020 23:58:24
User entered 'Yes (Y)'	System	27 Sep 2020 23:58:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '481113f5-1648-495d-8a32-a1b97ba8d2e5' User entered '97.4'	System	27 Sep 2020 23:58:24
	System	27 Sep 2020 23:58:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '481113f5-1648-495d-8a32-a1b97ba8d2e5'	System	27 Sep 2020 23:58:24
User entered 'No (N)'	System	27 Sep 2020 23:58:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '481113f5-1648-495d-8a32-a1b97ba8d2e5'	System	27 Sep 2020 23:58:24
User entered '27 Sep 2020 19:58'	System	27 Sep 2020 23:58:24

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 7'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:13', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '52594917-fb08-4441-8413-89724ca29a9c'	System	28 Sep 2020 23:09:33
User entered 'Yes (Y)'	System	28 Sep 2020 23:09:33

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:22', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '52594917-fb08-4441-8413-89724ca29a9c'	System	28 Sep 2020 23:09:33
User entered '98.2'	System	28 Sep 2020 23:09:33

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:26', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '52594917-fb08-4441-8413-89724ca29a9c'	System	28 Sep 2020 23:09:33
User entered 'No (N)'	System	28 Sep 2020 23:09:33

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:30', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '52594917-fb08-4441-8413-89724ca29a9c'	System	28 Sep 2020 23:09:33
User entered '28 Sep 2020 19:09'	System	28 Sep 2020 23:09:33

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 11:55'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 14:25'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:06', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '56b1292d-66fd-4948-9f5f-888f1f0a6cb3'	System	23 Sep 2020 00:49:26
User entered 'None (1)'	System	23 Sep 2020 00:49:26

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '56b1292d-66fd-4948-9f5f-888f1f0a6cb3'	System	23 Sep 2020 00:49:26
User entered 'No (N)'	System	23 Sep 2020 00:49:26

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '56b1292d-66fd-4948-9f5f-888f1f0a6cb3'	System	23 Sep 2020 00:49:26
User entered 'No (N)'	System	23 Sep 2020 00:49:26

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:20', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '56b1292d-66fd-4948-9f5f-888f1f0a6cb3'	System	23 Sep 2020 00:49:26
User entered 'None (1)'	System	23 Sep 2020 00:49:26

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '56b1292d-66fd-4948-9f5f-888f1f0a6cb3'	System	23 Sep 2020 00:49:26
User entered '22 Sep 2020 20:49'	System	23 Sep 2020 00:49:26

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 15:20'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 2'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ccc3d20a-71a2-4a61-af38-6a2854f70c9a'	System	23 Sep 2020 21:54:18
User entered 'None (1)'	System	23 Sep 2020 21:54:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:53:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ccc3d20a-71a2-4a61-af38-6a2854f70c9a'	System	23 Sep 2020 21:54:18
User entered 'No (N)'	System	23 Sep 2020 21:54:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ccc3d20a-71a2-4a61-af38-6a2854f70c9a'	System	23 Sep 2020 21:54:18
User entered 'No (N)'	System	23 Sep 2020 21:54:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ccc3d20a-71a2-4a61-af38-6a2854f70c9a'	System	23 Sep 2020 21:54:18
User entered 'None (1)'	System	23 Sep 2020 21:54:18

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ccc3d20a-71a2-4a61-af38-6a2854f70c9a'	System	23 Sep 2020 21:54:18
User entered '23 Sep 2020 17:54'	System	23 Sep 2020 21:54:18

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 3'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:34', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '58abace6-5ac3-4e8a-b2e8-aba29181ffa4'	System	24 Sep 2020 23:24:57
User entered 'None (1)'	System	24 Sep 2020 23:24:57

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '58abace6-5ac3-4e8a-b2e8-aba29181ffa4'	System	24 Sep 2020 23:24:57
User entered 'No (N)'	System	24 Sep 2020 23:24:57

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '58abace6-5ac3-4e8a-b2e8-aba29181ffa4'	System	24 Sep 2020 23:24:57
User entered 'No (N)'	System	24 Sep 2020 23:24:57

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:47', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '58abace6-5ac3-4e8a-b2e8-aba29181ffa4'	System	24 Sep 2020 23:24:57
User entered 'None (1)'	System	24 Sep 2020 23:24:57

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '58abace6-5ac3-4e8a-b2e8-aba29181ffa4'	System	24 Sep 2020 23:24:57
User entered '24 Sep 2020 19:24'	System	24 Sep 2020 23:24:57

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 4'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '19b9b002-b7d3-4f0c-b886-61df71187b62'	System	26 Sep 2020 00:16:00
User entered 'None (1)'	System	26 Sep 2020 00:16:00

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:41', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '19b9b002-b7d3-4f0c-b886-61df71187b62'	System	26 Sep 2020 00:16:00
User entered 'No (N)'	System	26 Sep 2020 00:16:00

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '19b9b002-b7d3-4f0c-b886-61df71187b62'	System	26 Sep 2020 00:16:00
User entered 'No (N)'	System	26 Sep 2020 00:16:00

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:49', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '19b9b002-b7d3-4f0c-b886-61df71187b62'	System	26 Sep 2020 00:16:00
User entered 'None (1)'	System	26 Sep 2020 00:16:00

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:15:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '19b9b002-b7d3-4f0c-b886-61df71187b62'	System	26 Sep 2020 00:16:00
User entered '25 Sep 2020 20:15'	System	26 Sep 2020 00:16:00

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 5'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '142a744b-bda4-4690-9314-8c679cf90b27'	System	26 Sep 2020 23:52:50
User entered 'None (1)'	System	26 Sep 2020 23:52:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '142a744b-bda4-4690-9314-8c679cf90b27'	System	26 Sep 2020 23:52:50
User entered 'No (N)'	System	26 Sep 2020 23:52:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '142a744b-bda4-4690-9314-8c679cf90b27'	System	26 Sep 2020 23:52:50
User entered 'No (N)'	System	26 Sep 2020 23:52:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:39', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '142a744b-bda4-4690-9314-8c679cf90b27'	System	26 Sep 2020 23:52:50
User entered 'None (1)'	System	26 Sep 2020 23:52:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '142a744b-bda4-4690-9314-8c679cf90b27'	System	26 Sep 2020 23:52:50
User entered '26 Sep 2020 19:52'	System	26 Sep 2020 23:52:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 6'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '20a0fb11-0de5-4718-aded-96e12304d7b0'	System	27 Sep 2020 23:58:50
User entered 'None (1)'	System	27 Sep 2020 23:58:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '20a0fb11-0de5-4718-aded-96e12304d7b0'	System	27 Sep 2020 23:58:50
User entered 'No (N)'	System	27 Sep 2020 23:58:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '20a0fb11-0de5-4718-aded-96e12304d7b0'	System	27 Sep 2020 23:58:50
User entered 'No (N)'	System	27 Sep 2020 23:58:50

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:40', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '20a0fb11-0de5-4718-aded-96e12304d7b0'	System	27 Sep 2020 23:58:50
User entered 'None (1)'	System	27 Sep 2020 23:58:50

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:47', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '20a0fb11-0de5-4718-aded-96e12304d7b0'	System	27 Sep 2020 23:58:50
User entered '27 Sep 2020 19:58'	System	27 Sep 2020 23:58:50

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 7'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '131cbde1-e921-48e7-ae26-b8df93a36074'	System	28 Sep 2020 23:09:59
User entered 'None (1)'	System	28 Sep 2020 23:09:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:43', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '131cbde1-e921-48e7-ae26-b8df93a36074'	System	28 Sep 2020 23:09:59
User entered 'No (N)'	System	28 Sep 2020 23:09:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:49', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '131cbde1-e921-48e7-ae26-b8df93a36074'	System	28 Sep 2020 23:09:59
User entered 'No (N)'	System	28 Sep 2020 23:09:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '131cbde1-e921-48e7-ae26-b8df93a36074'	System	28 Sep 2020 23:09:59
User entered 'None (1)'	System	28 Sep 2020 23:09:59

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:09:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '131cbde1-e921-48e7-ae26-b8df93a36074'	System	28 Sep 2020 23:09:59
User entered '28 Sep 2020 19:09'	System	28 Sep 2020 23:09:59

US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 11:55'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 14:25'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:55', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:49:58', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'None (0)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:50:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered 'No (N)'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-22T20:50:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ce25cd5a-33de-4adc-92a5-12c1bf71fa3b'	System	23 Sep 2020 00:50:23
User entered '22 Sep 2020 20:50'	System	23 Sep 2020 00:50:23

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '22 Sep 2020 15:20'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 2'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:20', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:23', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:26', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:35', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'None (0)'	System	23 Sep 2020 21:54:47

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:40', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered 'No (N)'	System	23 Sep 2020 21:54:47

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-23T17:54:44', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '025c7d3a-581e-4ca1-849a-ba58b792a6fe'	System	23 Sep 2020 21:54:47
User entered '23 Sep 2020 17:54'	System	23 Sep 2020 21:54:47



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 3'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:24:58', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:08', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:11', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:15', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'None (0)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:19', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered 'No (N)'	System	24 Sep 2020 23:25:30

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-24T19:25:27', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd17cbee5-f9d3-4201-96fb-466f66f346b6'	System	24 Sep 2020 23:25:30
User entered '24 Sep 2020 19:25'	System	24 Sep 2020 23:25:30

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 4'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:28', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:44', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:47', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'None (0)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:16:57', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered 'No (N)'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-25T20:17:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'db087f27-a6ab-4591-a432-ea40c95a2cdb'	System	26 Sep 2020 00:17:07
User entered '25 Sep 2020 20:17'	System	26 Sep 2020 00:17:07

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 5'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8' User entered 'None (0)'	System	26 Sep 2020 23:53:17
	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:53', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'None (0)'	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'None (0)'	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:52:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'None (0)'	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:53:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'None (0)'	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:53:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'None (0)'	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:53:09', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8'	System	26 Sep 2020 23:53:17
User entered 'No (N)'	System	26 Sep 2020 23:53:17



**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-26T19:53:13', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '216ba8c0-afd3-490f-9bb7-c7313ee73ca8' User entered '26 Sep 2020 19:53'	System	26 Sep 2020 23:53:17
	System	26 Sep 2020 23:53:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 6'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:52', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:58:58', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:08', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:11', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'None (0)'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:15', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered 'No (N)'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-27T19:59:19', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8788608b-7d49-4865-afd8-257033a69495'	System	27 Sep 2020 23:59:21
User entered '27 Sep 2020 19:59'	System	27 Sep 2020 23:59:21

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 15:39:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 15:42:17

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	22 Sep 2020 15:42:17
User entered 'Day 7'	System	22 Sep 2020 15:42:17

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:04', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:08', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:11', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:17', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'None (0)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:21', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered 'No (N)'	System	28 Sep 2020 23:10:26

US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-09-28T19:10:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd34641f9-78a1-4bb7-8522-d80d68263807'	System	28 Sep 2020 23:10:26
User entered '28 Sep 2020 19:10'	System	28 Sep 2020 23:10:26

**US3202183**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 15:39:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 15:42:17



US3202183

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 15:39:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 15:42:17

US3202183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:31
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	29 Sep 2020 15:34:16

**US3202183**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:31
User entered '29 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	29 Sep 2020 15:34:16

US3202183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:31
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	29 Sep 2020 15:34:16

US3202183

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:12:31
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	29 Sep 2020 15:34:16

US3202183

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:14:17
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	29 Sep 2020 15:34:21

**US3202183**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	29 Sep 2020 15:34:21

**US3202183**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:50:14
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 15:22:32



US3202183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:50:11
User closed query 'source= 06OCT2020' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:49:10
Query 'source= 06OCT2020' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Jan 2021 19:40:21
User entered '6 Oct 2020' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Jan 2021 19:38:07
User opened query 'source= 06OCT2020' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:16:04
User entered '7 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 15:22:32

US3202183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:01:27
User closed query 'data entered does not reconcile with previous query. Please confirm as per source contact was not made.' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:01:24
Query 'data entered does not reconcile with previous query. Please confirm as per source contact was not made.' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	20 Jan 2021 16:41:56
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Teresa Deese (b) (4)	20 Jan 2021 16:41:52
User opened query 'data entered does not reconcile with previous query. Please confirm as per source contact was not made.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:49:48
User closed query 'source = subject was not reached' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:49:48
Query 'source = subject was not reached' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Jan 2021 19:38:16
User opened query 'source = subject was not reached' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:16:50
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 15:22:32

US3202183

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 16:01:30
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	20 Jan 2021 16:42:16
User entered 'subj didn't answer phone w 3 attempts' reason for change: Data Entry Error	Teresa Deese (b) (4)	20 Jan 2021 16:42:16
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	20 Jan 2021 16:41:52
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 15:22:32

US3202183

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:17:00
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	07 Oct 2020 15:22:38

**US3202183**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	07 Oct 2020 15:22:38

**US3202183**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:21:12
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	13 Oct 2020 18:18:17

US3202183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:21:12
User entered '13 Oct 2020'	Lilian Nukuna (b) (4) (b) (4)	13 Oct 2020 18:18:17

US3202183

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:21:12
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	13 Oct 2020 18:18:17



**US3202183**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:21:12
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	13 Oct 2020 18:18:17

US3202183

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:21:18
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	13 Oct 2020 18:18:21

**US3202183**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	13 Oct 2020 18:18:21

US3202183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:12
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:00:55

US3202183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:12
User entered '20 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:00:55

US3202183

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:12
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:00:55

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'VISIT3'	System	26 Oct 2020 19:00:55

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23



US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '20 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '11:12'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '20 Oct 2020 11:12'	System	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '97.6' F	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered 'Oral (Oral)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '78'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'bpm'	System	26 Oct 2020 19:02:23



US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '18'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'breaths/min'	System	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '135'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:46
User entered '94'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:23

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'mmHg'	System	26 Oct 2020 19:02:23

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01

US3202183

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01



US3202183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:52
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:32

US3202183

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:23:52
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:32

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:18
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:45

US3202183

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:18
User entered '20 Oct 2020'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:45

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:18
User entered '11:22'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:45

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '20 Oct 2020 11:22'	System	26 Oct 2020 19:02:45

US3202183

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:10:22
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:24:23
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:02:50

**US3202183**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered '1'	System	26 Oct 2020 19:02:50



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 64'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '14 Oct 2020 00:01'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '18 Oct 2020 23:59'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 71'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**Fever (Temperature  $\geq$  100.4°F/38°C)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '21 Oct 2020 00:01'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 02:34:30
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 07:12:23
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '25 Oct 2020 23:59'	System	14 Aug 2020 15:34:09



US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 78'	System	14 Aug 2020 15:34:09

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

[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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-10-28T10:28:30', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '231542d9-97da-4f13-81d7-fa1761c385bf'	System	28 Oct 2020 14:28:51
User entered 'No (N)'	System	28 Oct 2020 14:28:51

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

Have you been exposed to someone with 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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-10-28T10:28:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '231542d9-97da-4f13-81d7-fa1761c385bf'	System	28 Oct 2020 14:28:51
User entered 'No (N)'	System	28 Oct 2020 14:28:51

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-10-28T10:28:48', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '231542d9-97da-4f13-81d7-fa1761c385bf'	System	28 Oct 2020 14:28:51
User entered '28 Oct 2020 10:28:48'	System	28 Oct 2020 14:28:51

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '28 Oct 2020 00:01'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '01 Nov 2020 23:59'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 92'	System	14 Aug 2020 15:34:09

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

[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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-11T21:13:39', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50893f0e-325a-47f0-a208-e10d91a10126'	System	12 Nov 2020 02:14:00
User entered 'No (N)'	System	12 Nov 2020 02:14:00



US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

Have you been exposed to someone with 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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-11T21:13:45', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50893f0e-325a-47f0-a208-e10d91a10126'	System	12 Nov 2020 02:14:00
User entered 'No (N)'	System	12 Nov 2020 02:14:00

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**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-11T21:13:55', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50893f0e-325a-47f0-a208-e10d91a10126'	System	12 Nov 2020 02:14:00
User entered '11 Nov 2020 21:13:55'	System	12 Nov 2020 02:14:00

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '11 Nov 2020 00:01'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '15 Nov 2020 23:59'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered 'Day 99'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-18T11:26:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '98b28037-72aa-4aef-a439-607b73c765bd'	System	18 Nov 2020 16:26:32
User entered 'No (N)'	System	18 Nov 2020 16:26:32

US3202183

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:39:15

Have you been exposed to someone with 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)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-18T11:26:19', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '98b28037-72aa-4aef-a439-607b73c765bd'	System	18 Nov 2020 16:26:32
User entered 'No (N)'	System	18 Nov 2020 16:26:32

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-18T11:26:29', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '98b28037-72aa-4aef-a439-607b73c765bd'	System	18 Nov 2020 16:26:32
User entered '18 Nov 2020 11:26:29'	System	18 Nov 2020 16:26:32



**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '18 Nov 2020 00:01'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:34:18
Data entry locked.	System	14 Aug 2020 15:34:09
User entered '22 Nov 2020 23:59'	System	14 Aug 2020 15:34:09

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-11-23T13:45:52', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '42fd97b6-4ad9-4dd2-bb9a-9741ce153da4'	System	23 Nov 2020 18:46:13
User entered 'No (N)'	System	23 Nov 2020 18:46:13

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-11-23T13:45:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '42fd97b6-4ad9-4dd2-bb9a-9741ce153da4'	System	23 Nov 2020 18:46:13
User entered 'No (N)'	System	23 Nov 2020 18:46:13

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-23T13:46:09', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '42fd97b6-4ad9-4dd2-bb9a-9741ce153da4'	System	23 Nov 2020 18:46:13
User entered '23 Nov 2020 13:46:09'	System	23 Nov 2020 18:46:13

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-11-29T15:40:18', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd22cd10f-3eed-4c4b-941c-4226380fd800'	System	29 Nov 2020 20:40:34
User entered 'No (N)'	System	29 Nov 2020 20:40:34

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-11-29T15:40:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd22cd10f-3eed-4c4b-941c-4226380fd800'	System	29 Nov 2020 20:40:34
User entered 'No (N)'	System	29 Nov 2020 20:40:34

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-11-29T15:40:30', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd22cd10f-3eed-4c4b-941c-4226380fd800'	System	29 Nov 2020 20:40:34
User entered '29 Nov 2020 15:40:30'	System	29 Nov 2020 20:40:34

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-12-06T12:42:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50dea3db-f55a-4bad-8aac-9b49d549bbac'	System	06 Dec 2020 17:42:22
User entered 'No (N)'	System	06 Dec 2020 17:42:22



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-12-06T12:42:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50dea3db-f55a-4bad-8aac-9b49d549bbac'	System	06 Dec 2020 17:42:22
User entered 'No (N)'	System	06 Dec 2020 17:42:22

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-12-06T12:42:21', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '50dea3db-f55a-4bad-8aac-9b49d549bbac'	System	06 Dec 2020 17:42:22
User entered '06 Dec 2020 12:42:21'	System	06 Dec 2020 17:42:22

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-12-14T16:57:33', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '9ff3a183-fd45-4f8b-9e86-80f77e5e65ad'	System	14 Dec 2020 21:57:47
User entered 'No (N)'	System	14 Dec 2020 21:57:47

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-12-14T16:57:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '9ff3a183-fd45-4f8b-9e86-80f77e5e65ad'	System	14 Dec 2020 21:57:47
User entered 'No (N)'	System	14 Dec 2020 21:57:47

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-12-14T16:57:44', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '9ff3a183-fd45-4f8b-9e86-80f77e5e65ad'	System	14 Dec 2020 21:57:47
User entered '14 Dec 2020 16:57:44'	System	14 Dec 2020 21:57:47



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-12-20T12:45:46', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cc1a18fb-d6d4-4984-8dfb-e18acf6045fb'	System	20 Dec 2020 17:45:59
User entered 'No (N)'	System	20 Dec 2020 17:45:59

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-12-20T12:45:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cc1a18fb-d6d4-4984-8dfb-e18acf6045fb'	System	20 Dec 2020 17:45:59
User entered 'No (N)'	System	20 Dec 2020 17:45:59

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-12-20T12:45:57', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'cc1a18fb-d6d4-4984-8dfb-e18acf6045fb' User entered '20 Dec 2020 12:45:57'	System	20 Dec 2020 17:45:59
	System	20 Dec 2020 17:45:59

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2020-12-28T11:08:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '17d74337-17a8-45be-921e-0ec0acf2e454'	System	28 Dec 2020 16:08:17
User entered 'No (N)'	System	28 Dec 2020 16:08:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2020-12-28T11:08:09', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '17d74337-17a8-45be-921e-0ec0acf2e454'	System	28 Dec 2020 16:08:17
User entered 'No (N)'	System	28 Dec 2020 16:08:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2020-12-28T11:08:14', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '17d74337-17a8-45be-921e-0ec0acf2e454'	System	28 Dec 2020 16:08:17
User entered '28 Dec 2020 11:08:14'	System	28 Dec 2020 16:08:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-01-04T21:42:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd4f69b9d-98d7-45d6-ab07-6ef0cbad9642'	System	05 Jan 2021 02:42:25
User entered 'No (N)'	System	05 Jan 2021 02:42:25



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-01-04T21:42:16', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd4f69b9d-98d7-45d6-ab07-6ef0cbad9642'	System	05 Jan 2021 02:42:25
User entered 'No (N)'	System	05 Jan 2021 02:42:25

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-01-04T21:42:24', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd4f69b9d-98d7-45d6-ab07-6ef0cbad9642'	System	05 Jan 2021 02:42:25
User entered '04 Jan 2021 21:42:24'	System	05 Jan 2021 02:42:25

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-01-10T13:50:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ea5c4bfe-981f-44eb-9e09-920642193ca5'	System	10 Jan 2021 18:50:11
User entered 'No (N)'	System	10 Jan 2021 18:50:11

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-01-10T13:50:06', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ea5c4bfe-981f-44eb-9e09-920642193ca5'	System	10 Jan 2021 18:50:11
User entered 'No (N)'	System	10 Jan 2021 18:50:11

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-01-10T13:50:09', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'ea5c4bfe-981f-44eb-9e09-920642193ca5'	System	10 Jan 2021 18:50:11
User entered '10 Jan 2021 13:50:09'	System	10 Jan 2021 18:50:11



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-01-17T09:51:23', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '75c05c3f-de4b-4bdf-901c-50945c9c8990'	System	17 Jan 2021 14:51:39
User entered 'No (N)'	System	17 Jan 2021 14:51:39

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-01-17T09:51:32', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '75c05c3f-de4b-4bdf-901c-50945c9c8990'	System	17 Jan 2021 14:51:39
User entered 'No (N)'	System	17 Jan 2021 14:51:39

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-01-17T09:51:36', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '75c05c3f-de4b-4bdf-901c-50945c9c8990'	System	17 Jan 2021 14:51:39
User entered '17 Jan 2021 09:51:36'	System	17 Jan 2021 14:51:39

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-01-24T22:23:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '5a92fdfb-eb39-4ec5-a59c-b25b48fd1271'	System	25 Jan 2021 03:24:14
User entered 'No (N)'	System	25 Jan 2021 03:24:14

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-01-24T22:24:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '5a92fdfb-eb39-4ec5-a59c-b25b48fd1271'	System	25 Jan 2021 03:24:14
User entered 'No (N)'	System	25 Jan 2021 03:24:14

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-01-24T22:24:10', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '5a92fdfb-eb39-4ec5-a59c-b25b48fd1271'	System	25 Jan 2021 03:24:14
User entered '24 Jan 2021 22:24:10'	System	25 Jan 2021 03:24:14

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-02-04T12:30:56', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '54aa337b-aedf-481c-8afc-401ca3688176'	System	04 Feb 2021 17:31:11
User entered 'No (N)'	System	04 Feb 2021 17:31:11



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-02-04T12:31:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '54aa337b-aedf-481c-8afc-401ca3688176'	System	04 Feb 2021 17:31:11
User entered 'No (N)'	System	04 Feb 2021 17:31:11

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-02-04T12:31:07', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '54aa337b-aedf-481c-8afc-401ca3688176'	System	04 Feb 2021 17:31:11
User entered '04 Feb 2021 12:31:07'	System	04 Feb 2021 17:31:11

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-02-07T12:37:01', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd277f464-1589-4020-b9c5-5605c2423a87'	System	07 Feb 2021 17:37:16
User entered 'No (N)'	System	07 Feb 2021 17:37:16

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-02-07T12:37:07', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd277f464-1589-4020-b9c5-5605c2423a87'	System	07 Feb 2021 17:37:16
User entered 'No (N)'	System	07 Feb 2021 17:37:16

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-02-07T12:37:12', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd277f464-1589-4020-b9c5-5605c2423a87'	System	07 Feb 2021 17:37:16
User entered '07 Feb 2021 12:37:12'	System	07 Feb 2021 17:37:16



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-02-14T15:36:54', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f56da12e-7f33-4465-b233-fefca7c5a767'	System	14 Feb 2021 20:37:05
User entered 'No (N)'	System	14 Feb 2021 20:37:05

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-02-14T15:36:59', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f56da12e-7f33-4465-b233-fefca7c5a767'	System	14 Feb 2021 20:37:05
User entered 'No (N)'	System	14 Feb 2021 20:37:05

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-02-14T15:37:03', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f56da12e-7f33-4465-b233-fefca7c5a767'	System	14 Feb 2021 20:37:05
User entered '14 Feb 2021 15:37:03'	System	14 Feb 2021 20:37:05

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-02-21T11:11:05', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd3f90292-505f-453c-bac7-13887e0b9571'	System	21 Feb 2021 16:11:17
User entered 'No (N)'	System	21 Feb 2021 16:11:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-02-21T11:11:09', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd3f90292-505f-453c-bac7-13887e0b9571'	System	21 Feb 2021 16:11:17
User entered 'No (N)'	System	21 Feb 2021 16:11:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-02-21T11:11:15', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'd3f90292-505f-453c-bac7-13887e0b9571'	System	21 Feb 2021 16:11:17
User entered '21 Feb 2021 11:11:15'	System	21 Feb 2021 16:11:17

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-02-28T01:16:55', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f3dc6a17-2b79-4742-991a-efb1ffba3832'	System	28 Feb 2021 06:17:10
User entered 'No (N)'	System	28 Feb 2021 06:17:10



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-02-28T01:17:02', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f3dc6a17-2b79-4742-991a-efb1ffba3832'	System	28 Feb 2021 06:17:10
User entered 'No (N)'	System	28 Feb 2021 06:17:10

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-02-28T01:17:08', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'f3dc6a17-2b79-4742-991a-efb1ffba3832'	System	28 Feb 2021 06:17:10
User entered '28 Feb 2021 01:17:08'	System	28 Feb 2021 06:17:10

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-03-07T07:20:31', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '1cc45b54-420c-4164-a04c-4e6c0d18ae43'	System	07 Mar 2021 12:20:43
User entered 'No (N)'	System	07 Mar 2021 12:20:43

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-03-07T07:20:38', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '1cc45b54-420c-4164-a04c-4e6c0d18ae43'	System	07 Mar 2021 12:20:43
User entered 'No (N)'	System	07 Mar 2021 12:20:43

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-03-07T07:20:42', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '1cc45b54-420c-4164-a04c-4e6c0d18ae43'	System	07 Mar 2021 12:20:43
User entered '07 Mar 2021 07:20:42'	System	07 Mar 2021 12:20:43



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (2ed72324b680b65c)', Time: '2021-03-21T10:07:37', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '22cea8aa-aa2e-4ef6-b311-ed659e77f045'	System	21 Mar 2021 14:07:53
User entered 'No (N)'	System	21 Mar 2021 14:07:53

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (2ed72324b680b65c)', Time: '2021-03-21T10:07:41', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '22cea8aa-aa2e-4ef6-b311-ed659e77f045'	System	21 Mar 2021 14:07:53
User entered 'No (N)'	System	21 Mar 2021 14:07:53



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2ed72324b680b65c)', Time: '2021-03-21T10:07:50', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '22cea8aa-aa2e-4ef6-b311-ed659e77f045'	System	21 Mar 2021 14:07:53
User entered '21 Mar 2021 10:07:50'	System	21 Mar 2021 14:07:53

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-03-30T15:48:12-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fe8f272c-f803-4b5d-9082-6e9b7771c64d'	System	30 Mar 2021 19:48:26
User entered 'No (N)'	System	30 Mar 2021 19:48:26

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-03-30T15:48:17-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fe8f272c-f803-4b5d-9082-6e9b7771c64d'	System	30 Mar 2021 19:48:26
User entered 'No (N)'	System	30 Mar 2021 19:48:26

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-03-30T15:48:24-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fe8f272c-f803-4b5d-9082-6e9b7771c64d'	System	30 Mar 2021 19:48:26
User entered '30 Mar 2021 15:48:24'	System	30 Mar 2021 19:48:26

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-04T08:29:45-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8e5c7b93-cd3a-4af0-a392-8a72521c702c' User entered 'No (N)'	System	04 Apr 2021 12:29:53
	System	04 Apr 2021 12:29:53

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-04T08:29:49-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8e5c7b93-cd3a-4af0-a392-8a72521c702c' User entered 'No (N)'	System	04 Apr 2021 12:29:53

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-04T08:29:52-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '8e5c7b93-cd3a-4af0-a392-8a72521c702c' User entered '04 Apr 2021 08:29:52'	System	04 Apr 2021 12:29:53
	System	04 Apr 2021 12:29:53

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-11T11:42:27-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fc8c53d7-6b20-4b4f-8dfa-0481f7c00a4a' User entered 'No (N)'	System	11 Apr 2021 15:42:44
	System	11 Apr 2021 15:42:44

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-11T11:42:32-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fc8c53d7-6b20-4b4f-8dfa-0481f7c00a4a'	System	11 Apr 2021 15:42:44
User entered 'No (N)'	System	11 Apr 2021 15:42:44

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-11T11:42:39-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: 'fc8c53d7-6b20-4b4f-8dfa-0481f7c00a4a'	System	11 Apr 2021 15:42:44
User entered '11 Apr 2021 11:42:39'	System	11 Apr 2021 15:42:44

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-18T12:03:36-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c9eb528-e7cd-4b03-b9a9-1bb5da108fbb' User entered 'No (N)'	System	18 Apr 2021 16:07:00
	System	18 Apr 2021 16:07:00

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-18T12:03:41-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c9eb528-e7cd-4b03-b9a9-1bb5da108fbb' User entered 'No (N)'	System	18 Apr 2021 16:07:00
	System	18 Apr 2021 16:07:00



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-18T12:03:47-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c9eb528-e7cd-4b03-b9a9-1bb5da108fbb' User entered '18 Apr 2021 12:03:47'	System	18 Apr 2021 16:07:00
	System	18 Apr 2021 16:07:00

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-26T12:53:36-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c57ed1f-569d-4ae7-ac18-5d0a65a8cd9c'	System	26 Apr 2021 16:53:48
User entered 'No (N)'	System	26 Apr 2021 16:53:48

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

Have you been exposed to someone with 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 (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-26T12:53:39-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c57ed1f-569d-4ae7-ac18-5d0a65a8cd9c'	System	26 Apr 2021 16:53:48
User entered 'No (N)'	System	26 Apr 2021 16:53:48

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (834AEDA5-B4FA-4212-A9C5-80ADEF4D7455)', Time: '2021-04-26T12:53:42-04:00', User OID: 'PatientReportedOutcome (US3202183)', ODM File OID: '2c57ed1f-569d-4ae7-ac18-5d0a65a8cd9c' User entered '26 Apr 2021 12:53:42'	System	26 Apr 2021 16:53:48
	System	26 Apr 2021 16:53:48

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 07:12:23



**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 07:12:23

**US3202183**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 15:39:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 07:12:23
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 07:12:23



US3202183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:31:10
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	18 Nov 2020 16:34:17

**US3202183**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:31:10
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered '18 Nov 2020'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	18 Nov 2020 16:34:17

**US3202183**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:31:10
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	18 Nov 2020 16:34:17

US3202183

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:31:10
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered empty.	(b) (4) Lilian Nukuna (b) (4) (b) (4)	18 Nov 2020 16:34:17

US3202183

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:31:36
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:44:27
User entered 'Yes (Y)'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	18 Nov 2020 16:34:22

**US3202183**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 14:38:01
User entered 'I'	System	18 Nov 2020 16:34:22

**US3202183**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:31:47
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Dec 2020 17:56:51

**US3202183**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:31:47
User entered '20 Dec 2020'	(b) (4), (b) (6)	20 Dec 2020 17:56:51



**US3202183**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:31:47
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	20 Dec 2020 17:56:51

US3202183

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:31:47
User entered 'LVM for day 119 phone call.'	(b) (4), (b) (6)	20 Dec 2020 17:56:51

**US3202183**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:31:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Dec 2020 17:58:40

**US3202183**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User entered 'I'	System	20 Dec 2020 17:58:40

**US3202183**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:11:53
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	07 Mar 2021 17:45:22

**US3202183**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:11:53
User entered '20 Jan 2021'	zackery harmon (b) (4) (b) (4)	07 Mar 2021 17:45:22

US3202183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:11:53
Query 'Please verify as source states no contact made but source completed with answers to questions' canceled (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:11:50
User opened query 'Please verify as source states no contact made but source completed with answers to questions' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:35:21
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	07 Mar 2021 17:45:22

US3202183

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:11:53
User entered empty.	zackery harmon (b) (4) (b) (4)	07 Mar 2021 17:45:22



**US3202183**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:19
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 22:21:21

**US3202183**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User entered 'I'	System	19 Feb 2021 22:21:21

**US3202183**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:37:49
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 22:21:42

US3202183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:28
User closed query 'source = 22Feb2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:15:25
Query 'source = 22Feb2021, Please verify' answered with 'attempt made first on 19 feb w/o contact' (Site from CRA).	Teresa Deese (b) (4)	29 Mar 2021 20:38:47
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 20:38:33
User opened query 'source = 22Feb2021, Please verify' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:37:40
User entered '19 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 22:21:42

**US3202183**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:37:51
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	22 Feb 2021 19:53:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 22:21:42

US3202183

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:28
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	22 Feb 2021 19:53:50
User entered 'LVM'	(b) (4) Lilian Nukuna (b) (4) (b) (4)	19 Feb 2021 22:21:42

US3202183

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:04
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	22 Feb 2021 20:00:00

**US3202183**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:23:14
User entered 'I'	System	22 Feb 2021 20:00:00



**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:58
User entered 'Yes (Y)'	Teresa Deese (b) (4)	24 Mar 2021 15:12:28

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:58
User entered '24 Mar 2021'	Teresa Deese (b) (4)	24 Mar 2021 15:12:28

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[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 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:15:58
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	24 Mar 2021 15:12:28

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered 'VISIT4'	System	24 Mar 2021 15:12:28

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered 'No (N)'	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered empty.	System	31 Mar 2021 21:45:18



US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered empty.	System	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered empty.	System	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18



US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered empty.	System	31 Mar 2021 21:45:18

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:07
User entered empty.	Erica Osmundsen (b) (4)	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered empty.	System	31 Mar 2021 21:45:18

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25

US3202183

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:39:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:11
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:12:33

US3202183

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:11
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:12:33

US3202183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User closed query 'Per GCL LAB Recon: Immunogenicity: GCL has an 24MAR2021 sample Barcode# 1F653387345 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:46:43
Query 'Per GCL LAB Recon: Immunogenicity: GCL has an 24MAR2021 sample Barcode# 1F653387345 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' answered with 'UPDATED OL-D57 IN EDC AS VISITS WERE OVERLAPPING ON THIS DATE' (Site from DM).	Erica Osmundsen (b) (4)	16 Apr 2021 13:16:55
User opened query 'Per GCL LAB Recon: Immunogenicity: GCL has an 24MAR2021 sample Barcode# 1F653387345 labelled as OL-D57. If Visit 4 DAY 209 and OL-D57 was performed on the same day then, Per CCG, OL-phase sample is collected but Immunogenicity form is updated under both the visit as yes. Please confirm if the Visit 4Day209 and OL-D57 are overlapping visit then update the Immunogenicity data under OL-D57 visit or else confirm the correct visit label if the visits are not overlapping. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 08:00:10
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:16:17



US3202183

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Teresa Deese (b) (4)	24 Mar 2021 15:12:50

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:17
User entered '24 Mar 2021'	Teresa Deese (b) (4)	24 Mar 2021 15:12:50

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:17
User entered '10:19'	Teresa Deese (b) (4)	24 Mar 2021 15:12:50

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered '24 Mar 2021 10:19'	System	24 Mar 2021 15:12:50

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:16:23
User entered 'Yes (Y)'	Teresa Deese (b) (4)	24 Mar 2021 15:12:40

**US3202183**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:56:25
User entered 'I'	System	24 Mar 2021 15:12:40

US3202183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	19 Apr 2021 13:50:38
	(b) (4)	

US3202183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
	(b) (4)	
User entered '19 Apr 2021'	zackery harmon (b) (4)	19 Apr 2021 13:50:38
	(b) (4)	



**US3202183**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) zackery harmon (b) (4) (b) (4)	19 Apr 2021 13:50:38

US3202183

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
User entered empty.	(b) (4) zackery harmon (b) (4)	19 Apr 2021 13:50:38

US3202183

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
	(b) (4)	
User entered 'Yes (Y)'	zackery harmon (b) (4)	19 Apr 2021 13:50:41
	(b) (4)	

**US3202183**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 13:50:41

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:22
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:41

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:22
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:37:41

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:39:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:22
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:41

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 16:37:41



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:39:15**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:56
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 16:39:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:20

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:07:56
User closed query 'Per 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)	22 Apr 2021 18:47:12
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
Query 'Per 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 'done' (Site from DM).	(b) (4)	
	Teresa Deese (b) (4)	22 Apr 2021 16:40:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 16:39:50
User opened query 'Per 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)	22 Apr 2021 08:46:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:47:20

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:39:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:39:37
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:37:57

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:39:15**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '1'	System	20 Jan 2021 16:37:57

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'I'	System	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	20 Jan 2021 16:38:33
DataPoint set to visible.	System	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	20 Jan 2021 16:38:33
DataPoint set to visible.	System	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '13:02'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '13 Jan 2021 13:02'	System	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '36.8' C	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '82'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'bpm'	System	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '18'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'breaths/min'	System	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '120'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '85'	Teresa Deese (b) (4)	20 Jan 2021 16:38:33



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:38:33

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:39:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered empty.	System	20 Jan 2021 16:38:33
DataPoint set to visible.	System	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
Query 'source= 14:30, please verify' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:18
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:41:14
User opened query 'source= 14:30, please verify' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:41:00
User entered '13:30'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59



**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '13 Jan 2021 13:30'	System	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '36.7' C	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '86'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'bpm'	System	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '17'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'breaths/min'	System	20 Jan 2021 16:39:59



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '120'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:41:14
User entered '90'	Teresa Deese (b) (4)	20 Jan 2021 16:39:59

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mmHg'	System	20 Jan 2021 16:39:59

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:06
User entered 'No (N)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:06

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:06
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:40:06

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:25

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:40:25



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered empty.	Teresa Deese (b) (4)	20 Jan 2021 16:40:25

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'mRNA-1273'	System	20 Jan 2021 16:40:25
DataPoint set to visible.	System	20 Jan 2021 16:37:57

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:40:25

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered '13:20'	Teresa Deese (b) (4)	20 Jan 2021 16:40:25

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '13 Jan 2021 13:20'	System	20 Jan 2021 16:40:25

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:25

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:42:17
User entered 'ONCE'	System	20 Jan 2021 16:40:25

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'INTRAMUSCULAR'	System	20 Jan 2021 16:40:25



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:21
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:36

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:21
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:40:36

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:21
User entered '13:19'	Teresa Deese (b) (4)	20 Jan 2021 16:40:36

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '13 Jan 2021 13:19'	System	20 Jan 2021 16:40:36

US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:26
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:49

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:26
User entered '13 Jan 2021'	Teresa Deese (b) (4)	20 Jan 2021 16:40:49

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:26
User entered '13:17'	Teresa Deese (b) (4)	20 Jan 2021 16:40:49

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 15:39:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered '13 Jan 2021 13:17'	System	20 Jan 2021 16:40:49



US3202183

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:39:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:42:30
User entered 'Yes (Y)'	Teresa Deese (b) (4)	20 Jan 2021 16:40:56

**US3202183**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:57:07
User entered 'I'	System	20 Jan 2021 16:40:56

**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:17:30
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:26:51

**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:17:30
User entered '20 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:26:51

US3202183

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:39:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:17:30
User closed query 'please confirm as source = contact not made' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:17:27
Query 'please confirm as source = contact not made' answered with 'look at source again' (Site from CRA).	Teresa Deese (b) (4)	29 Mar 2021 20:37:17
User opened query 'please confirm as source = contact not made' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:43:08
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:58:41
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:26:51

**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:17:30
User entered 'LEFT A VOICE MESSAGE. Subject called back' reason for change: Data Entry Error	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:58:34
User entered 'left a voice message'	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:26:51

**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:43:18
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	20 Jan 2021 20:27:09

**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'I'	System	20 Jan 2021 20:27:09



**US3202183**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered '1'	System	20 Jan 2021 20:27:09
DataPoint set to visible.	System	20 Jan 2021 20:27:09

**US3202183**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:43:43
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:57:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:43:43
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:57:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:43:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Feb 2021 20:57:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'OLD29'	System	24 Feb 2021 20:57:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:59:26



**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '10:10'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered '24 Feb 2021 10:10'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '36.8' C	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '92'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'bpm'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '16'	(b) (4), (b) (6)	24 Feb 2021 20:59:26



US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'breaths/min'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '116'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'mmHg'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '78'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'mmHg'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 20:59:26



**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '10:52'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered '24 Feb 2021 10:52'	System	24 Feb 2021 20:59:26

US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '36.6' C	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '87'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'bpm'	System	24 Feb 2021 20:59:26

US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '17'	(b) (4), (b) (6)	24 Feb 2021 20:59:26



US3202183

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'breaths/min'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '138'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'mmHg'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:44:02
User entered '88'	(b) (4), (b) (6)	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'mmHg'	System	24 Feb 2021 20:59:26

**US3202183**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:39:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:03
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 20:59:36

**US3202183**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:39:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:03
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 20:59:36

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 21:00:04



**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 21:00:04

US3202183

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'mRNA-1273'	System	24 Feb 2021 21:00:04
DataPoint set to visible.	System	20 Jan 2021 20:27:09

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered '24 Feb 2021'	(b) (4), (b) (6)	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered '10:14'	(b) (4), (b) (6)	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered '24 Feb 2021 10:14'	System	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 15:39:15**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
DataPoint Verified.	(b) (4), (b) (6)	26 Mar 2021 17:45:18
User entered 'ONCE'	System	24 Feb 2021 21:00:04



US3202183

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:39:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'INTRAMUSCULAR'	System	24 Feb 2021 21:00:04

**US3202183**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 21:00:09

**US3202183**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'I'	System	24 Feb 2021 21:00:09

**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:50
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 22:04:51

**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:50
User entered '3 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 22:04:51

**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:50
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 22:04:51

**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 15:39:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:50
User entered 'left a voice message'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 22:04:51

**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:45:54
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	03 Mar 2021 22:04:55



**US3202183**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 15:39:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:48:44
User entered 'I'	System	03 Mar 2021 22:04:55

**US3202183**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:05
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:07

**US3202183**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:05
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '24 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:07

**US3202183**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:05
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Clinic (Clinic)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:07

**US3202183**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 15:39:15**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	16 Apr 2021 13:16:07

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11



**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:16:11

US3202183

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:16:11

US3202183

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:16:11



US3202183

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:39:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:14
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:11

**US3202183**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 15:39:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 13:16:11

US3202183

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:39:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:21
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:15

**US3202183**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 15:39:15**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:21
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:15

US3202183

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:28
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:24

US3202183

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:39:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:28
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '24 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:24



**US3202183**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 13:34:28
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '10:19'	(b) (4) Erica Osmundsen (b) (4)	16 Apr 2021 13:16:24

**US3202183**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 15:39:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '24 Mar 2021 10:19'	System	16 Apr 2021 13:16:24

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 15:39:15**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:38:26
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
Signature has been broken.	(b) (4)	
	Teresa Deese (b) (4)	24 Mar 2021 15:14:19
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:14:19
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:08:59
	(b) (4)	
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:07:52
	(b) (4)	

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	16 Apr 2021 17:09:47
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:32:22
User entered 'USA-US128-2021-mRNA-1273-P301000012'	System	26 Mar 2021 13:36:29
User entered 'New'	(b) (4), (b) (6)	26 Mar 2021 13:36:29

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc degeneration, LLT: Cervical disc degeneration - version MedDRA\\23.0.	Coder Import (b) (4)	31 Mar 2021 10:26:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	(b) (4)	31 Mar 2021 10:26:21
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
Data point term sent to Coder	(b) (4)	24 Mar 2021 15:16:26
User entered 'worsening of cervical degenerative disc disease'	System	24 Mar 2021 15:15:39
	Teresa Deese (b) (4)	

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:32
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39



US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 15:17:03
User closed query 'PV Query: Please consider updating event onset date to the date subject symptoms of 'worsening of cervical degenerative disc disease began.' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:12:30
Query 'PV Query: Please consider updating event onset date to the date subject symptoms of 'worsening of cervical degenerative disc disease began.' answered with 'did not worsen since start of study-medical history item with planned surgery requiring overnight hospitalization thus requiring it to be reported as sae' (Site from Safety).	Erica Osmundsen (b) (4)	14 Apr 2021 04:41:08
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 15:22:20
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:39
User opened query 'PV Query: Please consider updating event onset date to the date subject symptoms of 'worsening of cervical degenerative disc disease began.' (Site from Safety).	(b) (4), (b) (6)	03 Apr 2021 00:02:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '1 Mar 2021'	(b) (4)	
	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:41
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:42
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 13:32:38
User closed query 'source = 01Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 13:32:36
Query 'source = 01Mar2021, please verify' answered with 'updated' (Site from CRA).	Erica Osmundsen (b) (4)	16 Apr 2021 19:40:58
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 19:40:42
User entered '1 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 19:40:42
User opened query 'source = 01Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:06:17
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
DataPoint Un-verified.	(b) (4)	
	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:26
Signature has been broken.	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:26
User entered '2 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:26
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:44
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '1 Mar 2021'	(b) (4)	
	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:32:58
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39



US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:01
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Mar 2021 16:51:50
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:08
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:10
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:11
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '1' reason for change: Data Entry Error	(b) (4)	25 Mar 2021 16:51:50
User entered '0'	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:14
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '1 Mar 2021' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Mar 2021 16:51:50
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '2 Mar 2021' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Mar 2021 16:51:50
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:32
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	25 Mar 2021 16:51:50
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:15:39

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:36
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39



**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:37
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:39
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:44
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:42
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:51
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

US3202183

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 11:09:44
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'UPDATED ConMeds to include general anesthesia as no other medication details provided in medical records' (Site from DM). DataPoint Verified.	Erica Osmundsen (b) (4)	15 Apr 2021 20:06:47
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:33:53
User signature succeeded.	(b) (4)	03 Apr 2021 05:22:49
User entered 'I'	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
	Teresa Deese (b) (4)	24 Mar 2021 15:15:39



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:56
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'I'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:58
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:33:59
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:15:39

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:09:42
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:09:39
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 17:09:35
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:52
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	16 Apr 2021 13:42:37



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:08
Signature has been broken.	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:08
User entered 'SUBJECT REPORTS DEGENERATIVE DISC DISEASE HAS BEEN PART OF HER MEDICAL HISTORY FOR 20 YEARS AND HASN'T ACTUALLY WORSENERD SINCE START OF STUDY, BUT THE ELECTIVE SURGICAL TREATMENT WAS POSTPONED DUE TO PANDEMIC. THE SURGERY REQUIRED AN OVERNIGHT STAY IN HOSPITAL FOR CERVICAL DISC REPLACEMENT AND PER PROTOCOL MUST BE ENTERED AS AN SAE DUE TO THIS HOSPITALIZATION. SUBJECT'S MEDICAL RECORDS WERE RECEIVED BUT CONSISTED MAINLY OF THE PROCEDURE NOTES AS THIS WAS A A SURGI-CENTER PART OF MEDICAL FACILITY. BASIC HEMATOLOGY AND CHEMISTRY LABS COLLECTED ON 25FEB2021 (-4 DAYS FROM SURGERY) WERE INCLUDED IN RECORDS. SHE WAS NEGATIVE FOR MRSA AND NOT TESTED FOR COVID-19 PER RECORDS. THE ONLY ABNORMAL VALUES ON SAFETY LABS WERE NOT NOTED AS SIGNIFICANT BY REVIEWING INVESTIGATOR. abnormalities were as follows (ref ranges in parenthesis and units of value and ref range following parenthetical info): MPV-11.7 (6.6 -10.6) fL, CO2 total- 32 (22 - 30) mmol/L, ANION gap-9.2 (10.0 - 20.0) MMOL/L, glucose 66 (74 - 106) mg/dL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 20:27:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'only surgical notes available because this was completed in day surgery/ short term surgery part of hospital. the pre-admission labs were including with records so I'll update narrative with that information.' (Site from Safety).	Erica Osmundsen (b) (4)	15 Apr 2021 20:15:20
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No mention of COVID-19 testing in medical records as subject had no symptoms and this was a planned procedure with overnight observation ' (Site from Safety).	Erica Osmundsen (b) (4)	15 Apr 2021 20:12:56
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:34:02
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	03 Apr 2021 00:03:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	03 Apr 2021 00:02:37
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Apr 2021 00:01:37
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:39:15

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT REPORTS DEGENERATIVE DISC DISEASE HAS BEEN PART OF HER MEDICAL HISTORY FOR 20 YEARS AND HASN'T ACTUALLY WORSENERD SINCE START OF STUDY, BUT THE ELECTIVE SURGICAL TREATMENT WAS POSTPONED DUE TO PANDEMIC. THE SURGERY REQUIRED AN OVERNIGHT STAY IN HOSPITAL FOR CERVICAL DISC REPLACEMENT AND PER PROTOCOL MUST BE ENTERED AS AN SAE DUE TO THIS HOSPITALIZATION.' reason for change: Data Entry Error User entered empty.	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	25 Mar 2021 16:51:50
	Teresa Deese (b) (4) [REDACTED] [REDACTED]	24 Mar 2021 15:15:39



**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Mar 2021 16:51:50
User entered '0'	System	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 15:15:39

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Mar 2021 16:51:50

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 15:30:33
User closed query 'source = "Acute" post surgical Neck Pain, please reconcile' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 15:30:19
User coded data point as SOC: Injury, poisoning and procedural complications, HLT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:06:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	07 Apr 2021 05:06:49
	(b) (4)	
Data point term sent to Coder	System	06 Apr 2021 15:07:07
Query 'source = "Acute" post surgical Neck Pain, please reconcile' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	06 Apr 2021 15:07:00
Signature has been broken.	Teresa Deese (b) (4)	06 Apr 2021 15:06:50
User entered 'acute POST SURGICAL PAIN IN CERVICAL NECK' reason for change: Data Entry Error	Teresa Deese (b) (4)	06 Apr 2021 15:06:50
User opened query 'source = "Acute" post surgical Neck Pain, please reconcile' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:35:08
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 14:34:41
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:34:37
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 15:17:26
User entered 'post surgical pain in cervical neck'	Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:09
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:11
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:13
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

US3202183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:15
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '2 Mar 2021'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37



**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:21
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:22
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:44
DataPoint Un-verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:21
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:26
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:28
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:29
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:31
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37



**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:33
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:35
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:36
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:38
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:40
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:42
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

US3202183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:44
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:46
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37



US3202183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:48
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:52
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

US3202183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:55
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

US3202183

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:39:15

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:57
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:35:59
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'I'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:01
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered '0'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37



**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:48
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:51
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:36:53
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:56:12
User entered empty.	(b) (4) Teresa Deese (b) (4)	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	24 Mar 2021 15:16:37

**US3202183**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Mar 2021 15:16:37

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:39:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User closed query 'Discharge summary also = HCTZ, Lipitor, and Calcium Polycarbophil- please confirm and update' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:08:01
Query 'Discharge summary also = HCTZ, Lipitor, and Calcium Polycarbophil- please confirm and update' answered with 'SUBJECT STATES SHE DISCONTINUED HCTZ IN NOVEMBER 2020 AND IS NOT TAKING CALCIUM POLYCARBOPHIL EITHER AS SHE FELT IT COULD INHIBIT HEALING. LIPITOR IS LISTED AS ATORVASTATIN' (Site from CRA).	Erica Osmundsen (b) (4)	15 Apr 2021 19:49:17
User opened query 'Discharge summary also = HCTZ, Lipitor, and Calcium Polycarbophil- please confirm and update' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:27:36
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
User closed query 'source = Flu vaccine, Pnuemonia Vaccine, and Tetanus vaccine in V2 notes. Please add to con meds and print e-pip regarding dosing for chart. Please report PD for receiving outside vaccinations within 28 days before or after study dosing (within 14 days before or after dosing for flu shot).' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:48:58
Query 'source = Flu vaccine, Pnuemonia Vaccine, and Tetanus vaccine in V2 notes. Please add to con meds and print e-pip regarding dosing for chart. Please report PD for receiving outside vaccinations within 28 days before or after study dosing (within 14 days before or after dosing for flu shot).' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Jan 2021 19:44:39
User opened query 'source = Flu vaccine, Pnuemonia Vaccine, and Tetanus vaccine in V2 notes. Please add to con meds and print e-pip regarding dosing for chart. Please report PD for receiving outside vaccinations within 28 days before or after study dosing (within 14 days before or after dosing for flu shot).' (Site from CRA).	(b) (4), (b) (6)	07 Jan 2021 18:52:46
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:25:08

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:39:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User closed query 'Per ConMed List, subject is taking hydrochlorothiazide. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:43:54
User closed query 'Please confirm drug status (whether on-going or no longer taking). ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:43:47
Query 'Per ConMed List, subject is taking hydrochlorothiazide. Please confirm and update if necessary.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:24:39
Query 'Please confirm drug status (whether on-going or no longer taking). ' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:24:34
User opened query 'Per ConMed List, subject is taking hydrochlorothiazide. Please confirm and update if necessary.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:55:24
Query 'Per ConMed List, subject is taking hydrochlorothiazide.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:55:09
User opened query 'Per ConMed List, subject is taking hydrochlorothiazide.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:54:59
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:53:59
User opened query 'Please confirm drug status (whether on-going or no longer taking). ' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:53:57
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:18:03
User closed query 'please verify and confirm documentation of start dates, indications, and dosage' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 22:08:50
Query 'please verify and confirm documentation of start dates, indications, and dosage' answered with 'DONE' (Site from CRA).	Erica Osmundsen (b) (4)	19 Oct 2020 18:38:54
User opened query 'please verify and confirm documentation of start dates, indications, and dosage' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:22:47
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:42:26

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND CALCIUM CHANNEL BLOCKERS, PRODUCT: AMLODIPINE BESILATE;BENAZEPRIL HYDROCHLORIDE, PRODUCTSYNONYM: AMLODIPINE/BENAZEPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:44:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:44:50
Data point term sent to Coder	System	23 Sep 2020 12:44:04
User entered 'Amlodipine/Benazepril'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:29:50
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:30:21
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:24:00
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:22:30
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:13
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Hypertension'	Tiffany Jewell (b) (4)	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '10/20'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2010'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:43:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:43:25



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:43:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:45:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:45:54
Data point term sent to Coder	System	23 Sep 2020 12:45:05
User entered 'Baclofen'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:04
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:30:45
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:23:54
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:22:54
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:22:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Osteoarthritis'	Tiffany Jewell (b) (4)	23 Sep 2020 12:44:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '10'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'as needed (PRN)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN Mar 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 18:49:56
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:20:14
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:41
User closed query 'hospital discharge medications = stop taking this medication, 02Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:08:28
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
Query 'hospital discharge medications = stop taking this medication, 02Mar2021, please verify' answered with 'corrected' (Site from CRA).	(b) (4)	
Query 'hospital discharge medications = stop taking this medication, 02Mar2021, please verify' answered with 'corrected' (Site from CRA).	Erica Osmundsen (b) (4)	15 Apr 2021 18:50:02
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Apr 2021 18:49:56
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	15 Apr 2021 18:49:45
User entered '02 Mar 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 18:49:45
User opened query 'hospital discharge medications = stop taking this medication, 02Mar2021, please verify' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 15:20:54
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 15:20:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 12:44:25
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:44:25



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User entered empty.	System	23 Sep 2020 12:44:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User entered empty.	System	23 Sep 2020 12:44:25

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:39
User entered empty.	System	23 Sep 2020 12:44:25

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
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) (b) (4)	23 Sep 2020 12:46:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:46:57
Data point term sent to Coder	System	23 Sep 2020 12:46:05
User entered 'Gabapentin'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:16
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:31:07
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:23:47
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:24:14
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:24:02
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Osteoarthritis'	Tiffany Jewell (b) (4)	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '300'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:45:18

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:45:18

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:26:53
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:24:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User closed query 'please verify as source = Vitamin B, Osteo Bi-Flex, Cinnamon, Hair Skin and Nails, Memordine' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 22:07:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:28:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Oct 2020 18:28:28
Data point term sent to Coder	System	19 Oct 2020 18:27:23
Query 'please verify as source = Vitamin B, Osteo Bi-Flex, Cinnamon, Hair Skin and Nails, Memordine' answered with 'SUBJECT LISTED MULTIVITAMIN AS WELL AS THE OTHER SUPPLEMENTS NOTED IN QUERY' (Site from CRA).	Erica Osmundsen (b) (4)	19 Oct 2020 18:27:11
Coding entries removed.	Erica Osmundsen (b) (4)	19 Oct 2020 18:27:08
User entered 'MULTI-VITAMIN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:27:08
User opened query 'please verify as source = Vitamin B, Osteo Bi-Flex, Cinnamon, Hair Skin and Nails, Memordine' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 15:21:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:24:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Sep 2020 11:24:42
Data point term sent to Coder	System	23 Sep 2020 12:47:06
User entered 'Multiple Vitamin'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:31:32
User closed query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:31:29
Query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 12:54:28
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	14 Nov 2020 12:54:24
User opened query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:28:47
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:27:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:46:10
	(b) (4)	



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General health supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 1970'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:46:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:46:10



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
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)	23 Sep 2020 12:49:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:49:57
Data point term sent to Coder	System	23 Sep 2020 12:49:08
User entered 'Trazadone'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:35
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:31:51
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 12:56:57
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:29:34
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:29:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Depression'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '150'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:30:45
DataPoint Un-verified.	zackery harmon (b) (4)	14 Nov 2020 12:56:34
User entered 'twice daily (BID)' reason for change:	(b) (4)	
New Information	zackery harmon (b) (4)	14 Nov 2020 12:56:34
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:48:17
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2018'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:31:19
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:31:55
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 12:56:52
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:30:20
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:30:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	14 Nov 2020 12:56:34
User entered '1'	System	23 Sep 2020 12:48:17



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:48:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:48:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
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)	23 Sep 2020 12:51:17
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:51:17
Data point term sent to Coder	System	23 Sep 2020 12:50:11
User entered 'Vitamin D3'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:32:24
User closed query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:32:16
Query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	14 Nov 2020 12:57:13
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	14 Nov 2020 12:57:10
User opened query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:31:16
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:30:52
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General health supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '50'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Other (OTHER)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'MCG'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2016'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:52:30
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:24:35
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:24:35
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:31:47
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:32:28
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 12:57:20
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:32:08
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:31:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:52:32
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:24:35
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:24:35
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User entered '1'	System	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User entered '1'	System	23 Sep 2020 12:49:31

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:46:52
User entered '804 (804)'	System	23 Sep 2020 12:49:31

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:27:31
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 19:51:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 19:51:23
Data point term sent to Coder DataPoint Un-verified.	System	15 Apr 2021 19:50:25
	Erica Osmundsen (b) (4)	15 Apr 2021 19:49:35
Coding entries removed.	Erica Osmundsen (b) (4)	15 Apr 2021 19:49:35
Signature has been broken.	Erica Osmundsen (b) (4)	15 Apr 2021 19:49:35
User entered 'ATORVASTATIN (LIPITOR)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 19:49:35
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 12:51:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 12:51:18
Data point term sent to Coder	System	23 Sep 2020 12:50:11

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Atorvastatin'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:32:04
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:32:52
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:05:23
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:32:35
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:32:17
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Hyperlipidemia'	Tiffany Jewell (b) (4)	23 Sep 2020 12:50:08



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '40'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2017'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:32:11
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:32:56
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:05:28
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:32:58
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:32:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:50:08

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:50:08

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: COXIBS, PRODUCT: CELECOXIB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:52:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:52:53
Data point term sent to Coder	System	23 Sep 2020 12:52:14
User entered 'Celecoxib'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:32:27
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:33:15
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:07:44
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:33:18
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:33:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Osteoarthritis'	Tiffany Jewell (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '200'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2015'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:53:00
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:20:21
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:20:21
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:32:36
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:33:20
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:07:49
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:33:59
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:33:47
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:53:02
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:20:21
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:20:21
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:51:23

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User entered '1'	System	23 Sep 2020 12:51:23

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User entered '1'	System	23 Sep 2020 12:51:23



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:10
User entered '804 (804)'	System	23 Sep 2020 12:51:23

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:54:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:54:58
Data point term sent to Coder	System	23 Sep 2020 12:54:16
User entered 'Pantoprazole'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Gastroesophageal reflux disease'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '20'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN Mar 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Apr 2021 14:27:07
	(b) (4), (b) (6)	
User closed query 'Please verify as source has as ongoing' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:27:05
Query 'Please verify as source has as ongoing' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	29 Mar 2021 20:43:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 20:43:26
User opened query 'Please verify as source has as ongoing' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:53:44
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:20:50
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:20:50
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:32:48
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:33:46
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:24:12
	(b) (4)	
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:35:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:34:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:53:51
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:27:10
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 20:43:26
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:20:50
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:20:50
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:53:51



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:53:51

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:53:51

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:56:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 12:56:50
Data point term sent to Coder	System	23 Sep 2020 12:56:18
User entered 'Vitamin C'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:34:19
User closed query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:34:13
Query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:09:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	14 Nov 2020 13:09:23
	(b) (4)	
User opened query 'Per eCCGs, please enter vitamins/supplements a as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:35:26
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:56:10
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General Health supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '500'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 1970'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 14:27:22
User closed query 'please verify as ongoing per source' (Site from CRA).	(b) (4), (b) (6)	05 Apr 2021 14:27:20
Query 'please verify as ongoing per source' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	29 Mar 2021 20:43:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 20:43:48
User opened query 'please verify as ongoing per source' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:54:11
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:21:16
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:21:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:56:10
	(b) (4)	



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:27:24
User entered empty; reason for change Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 20:43:48
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:21:16
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:21:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:56:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:56:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Nov 2020 21:49:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Nov 2020 21:49:48
Data point term sent to Coder	System	14 Nov 2020 13:13:17
Coding entries removed.	zackery harmon (b) (4)	14 Nov 2020 13:13:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: BILE ACID SEQUESTRANTS, PRODUCT: COLESTIPOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:06:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:06:45
Data point term sent to Coder	System	23 Sep 2020 12:59:22
User entered 'Colestipol'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:33:10
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:34:42
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 10:21:28
Query 'Please provide source.' answered with 'updated ' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:13:23
User entered 'Hyperlipedemia' reason for change: Data Entry Error	zackery harmon (b) (4)	14 Nov 2020 13:13:06
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:39:55
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:39:45
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'SUBJECT REPORTS THIS WAS PRESCRIBED TO PROTECT STOMACH AS BILE ACID SEQUESTRANT' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 18:30:35
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:38:49
User entered 'Gastroesophageal reflux disease'	Tiffany Jewell (b) (4)	23 Sep 2020 12:59:10



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'g (g)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '28 May 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:59
User closed query 'please verify as ongoing per source' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:08:57
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
Query 'please verify as ongoing per source' answered with 'confirmed and updated' (Site from CRA).	(b) (4)	
	Erica Osmundsen (b) (4)	15 Apr 2021 18:56:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 18:55:55
User opened query 'please verify as ongoing per source' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:54:38
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:21:39
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:21:39
DataPoint Verified.	(b) (4), (b) (6)	05 Jan 2021 20:33:54
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:34:46
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:13:29
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:40:23
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:40:14
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:01
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User entered empty; reason for change Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 18:55:55
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:21:39
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:21:39
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 12:59:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:59:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 12:59:10

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 12:59:10

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX, PRODUCTSYNONYM: B-COMPLEX [VITAMIN B COMPLEX] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:07:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Oct 2020 12:07:59
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN B-COMPLEX, INCL. COMBINATIONS, ATC: VITAMIN B-COMPLEX, PLAIN, PRODUCT: VITAMIN B COMPLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:27:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Sep 2020 15:27:37
Data point term sent to Coder	System	23 Sep 2020 13:01:23
User entered 'Vitamin B complex'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	17 Nov 2020 20:35:15
User closed query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:35:12
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' answered with 'UPDATED' (Site from CRA).	zackery harmon (b) (4) (b) (4)	14 Nov 2020 13:14:38
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4) (b) (4)	14 Nov 2020 13:13:52
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:44:12
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:40:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:05
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:35:35
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:14:41
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:48:45
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:48:25
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:43:59
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' canceled (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:43:58
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:43:47
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:43:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General Health Supplement'	Tiffany Jewell (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:14
User closed query 'Please enter dose in weight.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:35:25
Query 'Please enter dose in weight.' answered with 'subject states OTC vitamin supplement instructions state 1 tablet daily' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:16:15
User opened query 'Please enter dose in weight.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:45:13
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:44:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:16
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:44:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2016'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:54:58
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:06
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:55:00
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:06
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:00:24

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User entered '1'	System	23 Sep 2020 13:00:24

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User entered '1'	System	23 Sep 2020 13:00:24



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:18
User entered '804 (804)'	System	23 Sep 2020 13:00:24

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE, PRODUCTSYNONYM: OSTEO BI-FLEX [CHONDROITIN SULFATE;GLUCOSAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Jan 2021 21:12:42
Data point term sent to Coder	System	11 Jan 2021 19:30:55
Coding entries removed.	Teresa Deese (b) (4)	11 Jan 2021 19:30:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: CHONDROITIN SULFATE SODIUM;GLUCOSAMINE HYDROCHLORIDE, PRODUCTSYNONYM: OSTEO-BI-FLEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 15:40:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 15:40:39

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	23 Sep 2020 13:01:23
User entered 'Osteo bi flex'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:17
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:29
User closed query 'Per eCCGs, please enter vitamins/supplements as prophylaxis if preventative.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:37:43
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis if preventative.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:16:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	14 Nov 2020 13:16:45
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis if preventative.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:45:56
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:45:37
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 19:48:34
User closed query 'source=general health supplement' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 19:48:32
Query 'source=general health supplement' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	11 Jan 2021 19:30:53
User entered 'general HEALTH SUPPLEMENT' reason for change: Data Entry Error	Teresa Deese (b) (4)	11 Jan 2021 19:30:48
User opened query 'source=general health supplement' (Site from CRA).	(b) (4), (b) (6)	05 Jan 2021 20:37:00
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:37:46
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:18:14
User opened query 'Please provide source.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:48:10
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:47:56
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Bone Health supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:46
DataPoint Un-verified.	zackery harmon (b) (4)	14 Nov 2020 13:18:41
User entered '2' reason for change: Data Entry Error	(b) (4) zackery harmon (b) (4)	14 Nov 2020 13:18:41
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '1'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:34:48
User closed query 'Please enter dose in weight.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:37:49
Query 'Please enter dose in weight.' answered with 'subject states OTC vitamin supplement directions state take 2 tablets once a day' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:18:38
User opened query 'Please enter dose in weight.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:46:23
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2016'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:55:12
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:30
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:55:16
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:30
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:30
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User entered '1'	System	23 Sep 2020 13:01:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User entered '1'	System	23 Sep 2020 13:01:17

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:26
User entered '804 (804)'	System	23 Sep 2020 13:01:17

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CINNAMOMUM VERUM OIL, PRODUCTSYNONYM: CINNAMON OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 11:59:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 11:59:41
Data point term sent to Coder	System	23 Sep 2020 13:02:25
User entered 'Cinnamon'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:38:17
User closed query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:38:15
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:19:59
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	14 Nov 2020 13:19:55
	(b) (4)	
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:46
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:54
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:35:03
User closed query 'Please enter source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:38:22
Query 'Please enter source.' answered with 'updated ' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:20:37
User opened query 'Please enter source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:47:14
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:59
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:45
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:46:42
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General Health supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'I'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:35:08
User closed query 'Please provide source in weight.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:38:25
Query 'Please provide source in weight.' answered with 'Subject states General health supplement instructions state take one tab daily' (Site from CRA).	zackery harmon (b) (4) (b) (4)	14 Nov 2020 13:20:53
User opened query 'Please provide source in weight.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:47:31
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:47:16
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2019'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:35
User closed query 'please verify as source = ongoing' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 14:09:30
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
Query 'please verify as source = ongoing' answered with 'corrected' (Site from CRA).	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 18:57:00
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 18:56:54
User opened query 'please verify as source = ongoing' (Site from CRA).	(b) (4), (b) (6)	26 Mar 2021 17:55:38
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:53
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:34
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User entered empty; reason for change Data Entry Error	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 18:56:54
DataPoint Un-verified.	Teresa Deese (b) (4)	24 Mar 2021 15:22:53
User entered '22 Feb 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:22:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4)	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:01:54

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 13:01:54

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:52:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Oct 2020 20:52:23
Data point term sent to Coder	System	07 Oct 2020 20:22:29
User closed query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	System	07 Oct 2020 20:22:20
Query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' answered with 'updated' (Site from System).	Erica Osmundsen (b) (4)	07 Oct 2020 20:22:20
User entered 'biotin' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	07 Oct 2020 20:22:13
User opened query 'CDM Coding: Please provide the medication name and update the term with the generic and/or trade name to enable coding. Thank you' (Site from System).	Coder Import (b) (4) (b) (4)	29 Sep 2020 08:04:44
Data point term sent to Coder	System	23 Sep 2020 13:03:25
User entered 'Hair, skin and nails supplement'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:35:32
User closed query 'please confirm as this is a supplement and = prophylaxis per CCGs' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 18:39:02
Query 'please confirm as this is a supplement and = prophylaxis per CCGs' answered with 'UPDATED' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 17:33:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 17:32:54
User opened query 'please confirm as this is a supplement and = prophylaxis per CCGs' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:39:23
User closed query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:38:47
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4) (b) (4)	14 Nov 2020 13:23:29
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:49:25
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:49:19
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:35:36
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:39:27
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:23:32
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:49:35
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:49:27
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'General Health supplement'	Tiffany Jewell (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '5000' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	07 Oct 2020 20:22:13
User entered '1'	Tiffany Jewell (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'ug (ug)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	07 Oct 2020 20:22:13
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN UNK 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 20:35:41
User closed query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:39:30
Query 'Please provide source.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:24:26
User opened query 'Please provide source.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:50:58
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:50:48
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:02:47

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:02:47

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:02:47

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 13:02:47



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: MEMANTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:44:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 07:44:21
Data point term sent to Coder	System	19 Oct 2020 18:35:47
Coding entries removed.	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: OTHER ANTI-DEMENTIA DRUGS, PRODUCT: MEMANTINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:21:43
Data point term sent to Coder	System	23 Sep 2020 13:08:36
User entered 'Memantine'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	17 Nov 2020 20:40:46
User closed query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:40:42
Query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' answered with 'updated' (Site from CRA).	zackery harmon (b) (4)	14 Nov 2020 13:23:21
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	zackery harmon (b) (4)	14 Nov 2020 13:23:16
	(b) (4)	
User opened query 'Per eCCGs, please enter vitamins/supplements as prophylaxis.' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 17:51:20
DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 17:51:09
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:07:34
	(b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:22:53
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:34
User entered 'MEMORY SUPPLEMENT' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:26
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:39:52
User entered 'General health supplement'	Tiffany Jewell (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:23:06
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 17:21:24
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:44
User entered '10' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:26
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 06:40:13
User entered '1'	Tiffany Jewell (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'mg (mg)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	19 Oct 2020 18:35:26
User entered 'tablet (TABLET)'	Tiffany Jewell (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'once daily (QD)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Oral (ORAL)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'UN May 2020'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered '0'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 17:21:24
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:07:34



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Sep 2020 13:07:34

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Sep 2020 13:07:34

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:14
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:29:57
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' answered with 'PD noted. ePIP instructed not to delay dosin' (Site from DM).	Teresa Deese (b) (4)	18 Feb 2021 18:06:19
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:12:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:01:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:01:42
Data point term sent to Coder	System	11 Jan 2021 19:33:59

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'flu vaccine'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:16
User entered 'Yes (Y)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:19
User entered 'prophylaxis- flu'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:21
User entered '0.5'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:23
User entered 'mL (mL)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:40
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:43
User entered 'once (ONCE)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:45
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:49
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:50
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:52
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:54
User entered '0'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:57
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:56:59
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:00
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User entered empty.	System	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User entered empty.	System	11 Jan 2021 19:33:12

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:47:47
User entered empty.	System	11 Jan 2021 19:33:12

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:14
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:30:04
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' answered with 'see previous note' (Site from DM).	Teresa Deese (b) (4)	18 Feb 2021 18:06:33
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation. 4 days before dose 2' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:16:12
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE 13V, PRODUCTSYNONYM: PNEUMOCOCCAL 13 VALENT VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:15:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:15:42
Data point term sent to Coder	System	11 Jan 2021 19:44:07

PRODUCTION RELEASE (v12.003  
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2317 of 2484

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'pneumonia 13 vac'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:26
User entered 'Yes (Y)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:29
User entered 'prophylaxis- pneumonia'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:42
User entered '0.5'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:44
User entered 'mL (mL)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:45
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:47
User entered 'once (ONCE)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:50
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:52
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:54
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:43:27



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:55
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:57
User entered '0'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:57:59
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:58:01
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 17:58:03
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User entered empty.	System	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User entered empty.	System	11 Jan 2021 19:43:27

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:07
User entered empty.	System	11 Jan 2021 19:43:27



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:17
User closed query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.4 days before dose 2 ' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 14:30:12
Query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.4 days before dose 2 ' answered with 'see previous note' (Site from DM).	Teresa Deese (b) (4)	18 Feb 2021 18:06:43
User opened query 'Per MM, please confirm if the subject did not meet EC#9 (Has received or plans to receive a non-study vaccine within 28 days prior to or after any dose of IP (except for seasonal influenza vaccine which is not permitted within 14 days before or after any dose of IP). If met, please report as possible protocol deviation.4 days before dose 2 ' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:20:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: TETANUS VACCINES, PRODUCT: TETANUS VACCINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Jan 2021 21:24:43
Data point term sent to Coder	System	11 Jan 2021 19:45:08
User entered 'tetanus'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:18
User entered 'Yes (Y)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:19
User entered 'prophylaxis- tetanus'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:21
User entered '0.5'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:25
User entered 'mL (mL)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:26
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:28
User entered 'once (ONCE)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:29
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:44:14



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:31
User entered 'Intramuscular (INTRAMUSCULAR)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:33
User entered empty.	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:35
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:37
User entered '0'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:39
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:41
User entered '18 Sep 2020'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:43
User entered 'No (N)'	Teresa Deese (b) (4)	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User entered empty.	System	11 Jan 2021 19:44:14



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User entered empty.	System	11 Jan 2021 19:44:14

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:12
User entered empty.	System	11 Jan 2021 19:44:14

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:44:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 08:44:57
Data point term sent to Coder	System	24 Mar 2021 15:19:30
User entered 'tramadol'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:52
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:54
User entered 'post surgical cervical neck pain'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:57
User entered '50'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:29:58
User entered 'mg (mg)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:00
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:18:58



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:01
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:04
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:06
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:09
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:11
User entered '2 Mar 2021'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:13
User entered '0'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:14
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:17
User entered '9 Mar 2021'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:19
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User entered empty.	System	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User entered empty.	System	24 Mar 2021 15:18:58

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:16
User entered empty.	System	24 Mar 2021 15:18:58

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:25
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:37:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Mar 2021 14:37:08
Data point term sent to Coder	System	24 Mar 2021 15:20:31
User entered 'cyclobenzaprine'	Teresa Deese (b) (4) (b) (4) (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:27
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:29
User entered 'acute post surgical cervical neck pain'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:32
User entered '5'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:34
User entered 'mg (mg)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:35
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:38
User entered 'as needed (PRN)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:40
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:42
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:45
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:48
User entered '2 Mar 2021'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:50
User entered '0'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:52
User entered 'Yes (Y)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:54
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:19:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:30:56
User entered 'No (N)'	Teresa Deese (b) (4)	24 Mar 2021 15:19:45

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:19:45

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:19:45

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 15:19:45

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:18
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 19:55:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 19:55:14
Data point term sent to Coder	System	15 Apr 2021 19:53:31
User entered 'HYDROCHLOROTHIAZIDE'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:20
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:22
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'HYPERTENSION'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:23
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '25'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:24
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'mg (mg)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:26
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4)	15 Apr 2021 19:52:48
	Erica Osmundsen (b) (4)	

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:28
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'once daily (QD)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:30
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4)	15 Apr 2021 19:52:48
	Erica Osmundsen (b) (4)	

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:32
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Oral (ORAL)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:33
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4)	15 Apr 2021 19:52:48
	Erica Osmundsen (b) (4)	



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:35
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'UN UNK 2019'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:36
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:38
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:40
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'UN Nov 2020'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:42
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
User entered '1'	System	15 Apr 2021 19:52:48

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
User entered '1'	System	15 Apr 2021 19:52:48

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:39:15

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:31:54
User entered '804 (804)'	System	15 Apr 2021 19:52:48



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:02:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 13:02:03
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:48
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	16 Apr 2021 13:42:37
Data point term sent to Coder	System	15 Apr 2021 20:05:42
User entered 'GENERAL ENDOTRACHEAL ANESTHESIA'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:50
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Apr 2021 20:05:29
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	15 Apr 2021 20:05:29
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Apr 2021 20:05:19
User entered empty.	Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:51
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'WORSENING OF CERVICAL DEGENERATIVE DISC DISEASE'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:53
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'UNK'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:55
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Other (OTHER)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:56
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'UNKNOWN'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:21:58
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'once (ONCE)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:00
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19



US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:01
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:03
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered empty.	(b) (4)	
	Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:05
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '01 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:39:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:07
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '0'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:08
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:10
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered '01 Mar 2021'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:39:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:22:12
User signature succeeded.	Mark McKenzie (b) (4)	16 Apr 2021 13:42:37
User entered 'No (N)'	(b) (4) Erica Osmundsen (b) (4)	15 Apr 2021 20:05:19

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:39:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
User entered empty.	System	15 Apr 2021 20:05:19



**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
User entered empty.	System	15 Apr 2021 20:05:19

**US3202183**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 15:39:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 13:48:26
User entered empty.	System	15 Apr 2021 20:05:19

US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:39:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:21
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:31:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	24 Mar 2021 15:17:11
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	23 Sep 2020 13:07:43

US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:39:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:31:40
User entered '1 Mar 2021'	Teresa Deese (b) (4) [REDACTED] [REDACTED]	24 Mar 2021 15:17:36

US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:39:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:31:40
User entered 'cervical disc replacement'	Teresa Deese (b) (4)	24 Mar 2021 15:17:36

US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:39:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:31:40
User entered 'Adverse Event (AE)'	Teresa Deese (b) (4)	24 Mar 2021 15:17:36

US3202183

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:39:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:31:40
User entered empty.	Teresa Deese (b) (4)	24 Mar 2021 15:17:36

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'USA-US128-2021-MRNA-1273-P301000012'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Mark'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'McKenzie'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered 'US'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:11:21
User entered '2'	System	16 Apr 2021 17:10:20
User entered '1'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'USA-US128-2021-MRNA-1273-P301000012'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Mark'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'McKenzie'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered 'US'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:11:21
User entered '2'	System	16 Apr 2021 17:10:20
User entered '1'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 15:39:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered '26/Mar/2021 08:38'	System	26 Mar 2021 13:38:05



US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:39:15

**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.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered 'I'	(b) (4), (b) (6)	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'USA-US128-2021-MRNA-1273-P301000012'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Mark'	System	26 Mar 2021 13:36:29

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 15:39:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'McKenzie'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered 'US'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:11:21
User entered '2'	System	16 Apr 2021 17:10:20
User entered '1'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 15:39:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:33:01
User entered '16/Apr/2021 13:10'	System	16 Apr 2021 17:10:20

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:39:15

**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.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:33:01
User entered 'I'	(b) (4), (b) (6)	16 Apr 2021 17:10:20

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'USA-US128-2021-MRNA-1273-P301000012'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Yes (Y)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'No (N)'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'Mark'	System	26 Mar 2021 13:36:29



**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
Reviewed for Safety.	(b) (4), (b) (6)	26 Mar 2021 13:37:55
User entered 'McKenzie'	System	26 Mar 2021 13:36:29

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:26:26
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:38:38
User entered 'US'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 15:39:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	19 Apr 2021 13:11:21
User entered '2'	System	16 Apr 2021 17:10:20
User entered '1'	System	26 Mar 2021 13:38:05

**US3202183**

**Folder: SAE USA-US128-2021-MRNA-1273-P301000012**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 15:39:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:33:01
User entered '19/Apr/2021 06:11'	System	19 Apr 2021 13:11:21

US3202183

Folder: SAE USA-US128-2021-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:39:15

**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.	Mark McKenzie (b) (4)	22 Apr 2021 17:57:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 13:33:01
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 13:11:21