

US3202217 (Prod: WR-ClinSearch, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:43:30

All time stamps listed in this document are displayed in GMT

US3202217

Form: Participant Creation

Data signed: (b) (4) 09 Apr 2021 15:42:02

Generated On: 09 Jun 2021 15:43:30

[Participant ID](#)

US3202217

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

US3202217

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3202217

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Date of Birth (MMM yyyy)	(b) (6) 1945
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 02:13:25

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Date of Informed Consent (<i>dd MMM yyyy</i>)	17 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 02:13:25

Generated On: 09 Jun 2021 15:43:30

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 02:13:32

Generated On: 09 Jun 2021 15:43:30

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	CHRONIC NEUROPATHIC PAIN- LEFT HAND
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3202217

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	CHRONIC NEUROPATHIC PAIN LEFT LEG
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) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	GOUT
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	CARDIAC ARRHYTHMIA
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 (13)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	CHRONIC PAIN RIGHT KNEE
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 (14)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	RIGHT KNEE TORN MENISCUS REPAIR SURGERY
Start date (dd MMM yyyy)	UN APR 2020
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 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	ALLERGY TO BRAZIL NUTS
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	ALLERGY TO DOXYCYCLINE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	SCIATICA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	OSTEOARTHRITIS RIGHT KNEE
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 (19)

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Condition	SQUAMOUS CELL SKIN CANCER RIGHT ELBOW
Start date (dd MMM yyyy)	UN FEB 2020
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 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

US3202217

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	17 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:31
Height (<i>xxx.x</i>)	168.4 cm
Weight (<i>xxx.x</i>)	89.6 kg
BMI (<i>xxx.x</i>)	31.59540 kg/m ²
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 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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 02:13:32

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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

Visit date (dd MMM yyyy)	17 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3202217

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

What was the date of randomization? (dd MMM yyyy) 17 AUG 2020

What was the participant's randomization number? 186494

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 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 02:13:32

Generated On: 09 Jun 2021 15:43:30

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)	17 AUG 2020
Time of assessment (00:00-23:59)	09:31 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 09:31
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 AUG 2020
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	17 AUG 2020 10:48
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 02:13:32

Generated On: 09 Jun 2021 15:43:30

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) 17 AUG 2020

What was the treatment time? (00:00-23:59) 10:11 (24 HR)

Treatment Date and Time (derived) 17 AUG 2020 10:11

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 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 AUG 2020

Collection time (00:00-23:59)

09:41 (24 HR)

Collection date and time (derived)

17 AUG 2020 09:41

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)			17 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:39	17 AUG 2020 09:39
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 15:43:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 10:45

PC Open Date & Time

17 AUG 2020 10:31

PC Close Date & Time

17 AUG 2020 13:01

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.5 °F

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

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

PC Time Stamp	17 AUG 2020 21:53
PC Open Date & Time	17 AUG 2020 13:56
PC Close Date & Time	18 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 21:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

19 AUG 2020 22:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

97.4 °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

21 AUG 2020 17:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 20:23

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

23 AUG 2020 21:28

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 AUG 2020 10:46

PC Open Date & Time

17 AUG 2020 10:31

PC Close Date & Time

17 AUG 2020 13:01

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

17 AUG 2020 21:54

PC Open Date & Time

17 AUG 2020 13:56

PC Close Date & Time

18 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

18 AUG 2020 21:13

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

19 AUG 2020 22:01

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

21 AUG 2020 17:00

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

22 AUG 2020 20:24

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

23 AUG 2020 21:29

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 10:47
PC Open Date & Time	17 AUG 2020 10:31
PC Close Date & Time	17 AUG 2020 13:01

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

No ☒

Yes ☐

PC Time stamp	17 AUG 2020 21:54
PC Open Date & Time	17 AUG 2020 13:56
PC Close Date & Time	18 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

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)

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

		Yes <input type="checkbox"/>
PC Time stamp	18 AUG 2020 21:14	
PC Open Date & Time	18 AUG 2020 12:00	
PC Close Date & Time	19 AUG 2020 11:59	

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

59 of 2605

EAB) (1725)

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 22:02
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

61 of 2605

EAB) (1725)

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

Yes ☐

PC Time stamp

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 ☒

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 17:01
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 ☒

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 20:24
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 ☒

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 21:29
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3202217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 SEP 2020

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

Comments UNABLE TO REACH

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	14 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

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020
Time of assessment (00:00-23:59)	11:14 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 11:14
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020
Time of assessment (00:00-23:59)	12:31 (24 HR)
Vital Signs Date and Time (derived)	14 SEP 2020 12:31
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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.

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020

What was the treatment time? (00:00-23:59) 11:57 (24 HR)

Treatment Date and Time (derived) 14 SEP 2020 11:57

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

US3202217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 SEP 2020

Collection time (00:00-23:59)

11:23 (24 HR)

Collection date and time (derived)

14 SEP 2020 11:23

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)			14 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:21	14 SEP 2020 11:21
Nasopharyngeal Swab 2	No		

US3202217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

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

PC Time Stamp 14 SEP 2020 13:01

PC Open Date & Time 14 SEP 2020 12:17

PC Close Date & Time 14 SEP 2020 14:47

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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):

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

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

PC Time Stamp 14 SEP 2020 17:41

PC Open Date & Time 14 SEP 2020 15:42

PC Close Date & Time 15 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

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

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

PC Time Stamp 15 SEP 2020 16:52

PC Open Date & Time 15 SEP 2020 12:00

PC Close Date & Time 16 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

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

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 17 SEP 2020 18:00

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 18 SEP 2020 22:35

PC Open Date & Time 18 SEP 2020 12:00

PC Close Date & Time 19 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 ☒

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 SEP 2020 19:54

PC Open Date & Time 20 SEP 2020 12:00

PC Close Date & Time 21 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 13:03

PC Open Date & Time

14 SEP 2020 12:17

PC Close Date & Time

14 SEP 2020 14:47

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

14 SEP 2020 17:42

PC Open Date & Time

14 SEP 2020 15:42

PC Close Date & Time

15 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020 16:52

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020 18:01

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020 22:36

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 6

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 SEP 2020 19:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 13:03
PC Open Date & Time	14 SEP 2020 12:17
PC Close Date & Time	14 SEP 2020 14:47

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

No ☒

Yes ☐

PC Time stamp	14 SEP 2020 17:42
PC Open Date & Time	14 SEP 2020 15:42
PC Close Date & Time	15 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 ☒

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 16:52
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

Yes ☐

PC Time stamp

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

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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US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 18:01
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

109 of 2605

EAB) (1725)

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 22:36
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

EAB) (1725)

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US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 19:55
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3202217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:25

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	08:19 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 08:19
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3202217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3202217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

08:27 (24 HR)

Collection date and time (derived)

13 OCT 2020 08:27

US3202217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:13:32

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 OCT 2020 22:01:33

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

14 NOV 2020 08:11:42

Patient Cloud Open Date & Time

14 NOV 2020 00:01

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 13:30:15
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

26 NOV 2020 16:14:37

Patient Cloud Open Date & Time

25 NOV 2020 00:01

Patient Cloud Close Date & Time

29 NOV 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 DEC 2020 21:42:38
Patient Cloud Open Date & Time	02 DEC 2020 00:01
Patient Cloud Close Date & Time	06 DEC 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

12 DEC 2020 22:16:40

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 12:21:51
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	27 DEC 2020 22:42:01
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 138

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

30 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

07 JAN 2021 22:40:39

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

13 JAN 2021 22:10:03

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

20 JAN 2021 19:36:25

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

28 JAN 2021 16:29:01

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

05 FEB 2021 20:13:19

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	14 FEB 2021 09:56:44
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

18 FEB 2021 07:48:22

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

26 FEB 2021 02:55:40

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

06 MAR 2021 08:37:43

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 08:24:35

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	20 MAR 2021 22:01:10
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

28 MAR 2021 22:28:18

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

01 APR 2021 20:44:41

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 APR 2021 20:54:20
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 APR 2021 19:49:54
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	22 APR 2021 20:24:51
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

30 APR 2021 16:33:12

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

12 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	26 MAY 2021 00:01
Patient Cloud Close Date & Time	30 MAY 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	16 JUN 2021 00:01
Patient Cloud Close Date & Time	20 JUN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	30 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	21 JUL 2021 00:01
Patient Cloud Close Date & Time	25 JUL 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Open Date & Time](#)

25 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	08 SEP 2021 00:01
Patient Cloud Close Date & Time	12 SEP 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	15 SEP 2021 00:01
Patient Cloud Close Date & Time	19 SEP 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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°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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	17 NOV 2021 00:01
Patient Cloud Close Date & Time	21 NOV 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	01 DEC 2021 00:01
Patient Cloud Close Date & Time	05 DEC 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 481

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

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

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

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

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

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

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	08 DEC 2021 00:01
Patient Cloud Close Date & Time	12 DEC 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	15 DEC 2021 00:01
Patient Cloud Close Date & Time	19 DEC 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

02 FEB 2022 00:01

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06 FEB 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

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13 FEB 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

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20 FEB 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Patient Cloud Open Date & Time	23 FEB 2022 00:01
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US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

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06 MAR 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

30 MAR 2022 00:01

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03 APR 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

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

[Patient Cloud Open Date & Time](#)

06 APR 2022 00:01

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10 APR 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

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17 APR 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 621

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

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

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

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

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

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

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	01 JUN 2022 00:01
Patient Cloud Close Date & Time	05 JUN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUN 2022 00:01
Patient Cloud Close Date & Time	03 JUL 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 719

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

10 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

14 AUG 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	12 OCT 2022 00:01
Patient Cloud Close Date & Time	16 OCT 2022 23:59

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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"/>

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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	19 OCT 2022 00:01
Patient Cloud Close Date & Time	23 OCT 2022 23:59

US3202217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:43:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		27 FEB 2021 16:39:34

US3202217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 12:46:20

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

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

Comments LVM
SUB CALLED BACK

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 12:46:20

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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

Visit date (dd MMM yyyy)	19 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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US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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) _____

US3202217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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.

US3202217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	12:08 (24 HR)
Collection date and time (derived)	19 MAR 2021 12:08

US3202217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:20:39

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 15 Apr 2021 19:20:39

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 15 Apr 2021 19:20:39

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3202217

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:43:30

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3202217

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:43:30

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3202217

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

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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

Visit date (dd MMM yyyy)	25 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3202217

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Date of updated informed consent (<i>dd MMM yyyy</i>)	25 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>)	25 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

US3202217

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Height	
Weight	
BMI (xxx.x)	

US3202217

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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)	25 JAN 2021
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 08:30
Temperature (xxx.x)	37 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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)	25 JAN 2021
Time of assessment (00:00-23:59)	09:37 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 09:37
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)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

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

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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.

US3202217

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

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 08:48 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 08:48

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

US3202217

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 JAN 2021

Collection time (00:00-23:59)

08:46 (24 HR)

Collection date and time (derived)

25 JAN 2021 08:46

US3202217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	08:44
Collection Date and Time (derived)	25 JAN 2021 08:44

US3202217

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

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3202217

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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

US3202217

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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

Visit date (dd MMM yyyy)	1 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	OLD29
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US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	1 MAR 2021
Time of assessment (00:00-23:59)	14:46 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 14:46
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)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	1 MAR 2021
Time of assessment (00:00-23:59)	15:35 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 15:35
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3202217

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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.

US3202217

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 1 MAR 2021

What was the treatment time? (00:00-23:59) 14:57 (24 HR)

Treatment Date and Time (derived) 1 MAR 2021 14:57

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

US3202217

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 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

US3202217

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3202217

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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) _____

US3202217

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

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.

US3202217

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 MAR 2021
Collection time (00:00-23:59)	12:08 (24 HR)
Collection date and time (derived)	19 MAR 2021 12:08

US3202217

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Mar 2021 13:10:50

Generated On: 09 Jun 2021 15:43:30

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

AEID	USA-US128-2021-MRNA-1273-P30 1000020
Adverse event	WORSENING RIGHT KNEE OSTEOARTHRITIS
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)	11 FEB 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)	12 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	11 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	12 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	356 of 2605

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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	

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

HAD OUTPATIENT SURGERY
PER SUBJECT BUT UPON
RECEIPT OF RECORDS, IT WAS
LEARNED THAT THE SUBJECT
STAYED OVERNIGHT AT
HOSPITAL FOR POST-OP
OBSERVATION, THUS MAKING
THIS PLANNED SURGERY AN
SAE PER THIS PROTOCOL'S
GUIDELINES. NO SIGNIFICANT
ABNORMALITIES ON LABS OR
PATHOLOGY. RECORDS WERE
REDACTED AND SCANNED TO
SAFETY TEAM WHICH
INCLUDED LABS--SUMMARY
OF 12/FEB/2021 LABS THAT
WERE OUTSIDE NORMAL
RANGE (REF RANGE IN
PARENTHESES): GLUCOSE 137
(60-99) MG/DL; WBC 12.9
(4.5-10.5) K/UL; RBC 4.18 (4.7-6.1)
M/UL; H/H 13.0/38.3 (13.6-17.8)
G/DL/ 40-51) %; NEUT 11.18
(2.02-8.4) K/UL
LYMPH 0.61 (.67-4.3) K/UL

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)

Generated On: 09 Jun 2021 15:43:30

AEID

Adverse event

ACUTE POST-OPERATIVE PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

26 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (2)

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Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
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)	_____

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 09 Apr 2021 15:42:03

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

Yes ☒

No ☐

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

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication TRAZODONE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication CARDIAC ARRHYTHMIA

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 (4)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication CARDIAC ARRHYTHMIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB	2021
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication SPIRONOLACTONE

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 (6)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (7)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2012	
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) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication ALLOPURINOL

Prophylaxis Yes ☐
No ☒

Indication GOUT

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 (8)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NEUROPATHIC PAIN

Dose per administration 900

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 JUN 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) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication PERCOCET 7.5/325 MG

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NEUROPATHIC PAIN

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 (10)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	12 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication BARRETT'S ESOPHAGUS

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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US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 2012	
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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication VOLTARAN GEL- 1%
DICLOFENAC SODIUM

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN RIGHT KNEE

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication PREDNISOLONE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC BACK PAIN

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 (13)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)	18 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)	28 MAR 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) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication BUPROPION

Prophylaxis Yes ☐
No ☒

Indication CHRONIC NEUROPATHIC PAIN
IN LEFT LEG AND LEFT HAND

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication HYDRALAZINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication DEXMETHASONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING RIGHT KNEE
OSTEOARTHRITIS

Dose per administration 8

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 (16)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 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 (17)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication DOCUSATE SODIUM

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
OPIOID-INDUCED
CONSTIPATION POST-SURGERY

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 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 (18)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication BARRETT'S ESOPHAGUS

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 (18)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 12 FEB 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 (20)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication HYDROCODONE /
ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RIGHT KNEE
OSTEOARTHRITIS

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 (20)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 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) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐
No ☒

Indication WORSENING RIGHT KNEE
OSTEOARTHRITIS

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication SODIUM CHLORIDE 0.45%

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RIGHT KNEE
OSTEOARTHRITIS

Dose per administration 100

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

If dose unit is Other, specify ML/HOUR

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

If frequency is Other, specify CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		11 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication OXYCODONE (ROXICODONE)

Prophylaxis Yes ☐
No ☒

Indication ACUTE POST-OPERATIVE 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 ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication WARFARIN

Prophylaxis Yes ☒
No ☐

Indication BLOOD CLOT PROPHYLAXIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)		12 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 29 MAR 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication SPINAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF RIGHT KNEE
OSTEOARTHRITIS

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INJECTION TO SUBARACHNOID CEREBROSPINAL FLUID SPACE	
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	11 FEB 2021	
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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication TRANEXAMIC ACID

Prophylaxis Yes ☒
No ☐

Indication SURGICAL PROPHYLAXIS (TO
PREVENT BLOOD LOSS DUE TO
ANTICOAGULANT USE)

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 (26)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 FEB 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"/>

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication CARDIAC ARRHYTHMIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 17:58:10

Generated On: 09 Jun 2021 15:43:30

	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)	30 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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 15:42:03

Generated On: 09 Jun 2021 15:43:30

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 17:58:11

Generated On: 09 Jun 2021 15:43:30

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	RIGHT KNEE ARTHROPLASTY (RIGHT TOTAL KNEE REPLACEMENT)	Adverse Event	

US3202217

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:43:30

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 ☐

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

SAEID	USA-US128-2021-MRNA-1273-P301000020
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

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:30

SAEID	USA-US128-2021-MRNA-1273-P301000020
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 15:59
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

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:30

SAEID	USA-US128-2021-MRNA-1273-P301000020
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)	23/APR/2021 16:12
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

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:30

SAEID	USA-US128-2021-MRNA-1273-P301000020
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)	03/MAY/2021 08:26
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

US3202217 (Prod: WR-ClinSearch, LLC)

US3202217

Form: Participant Creation

Generated On: 09 Jun 2021 15:43:30

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Apr 2021 21:43:03
User entered 'US3202217'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:15:00

US3202217

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:42:14
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:53:41

US3202217

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:42:14
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:15:01

US3202217

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:42:14
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:53:41

US3202217

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'SCRN'	System	17 Aug 2020 13:53:41

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered (b) (6) 1945'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:15:02

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '75'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'YEARS'	System	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '75'	System	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered 'Male (M)'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:43:30

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:44:28
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:08:51

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered '17 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Aug 2020'	System	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2020'	System	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered 'Amendment 2 (2)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:05

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 20:17:06
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:15:01

US3202217

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:43:30

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'I'	System	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:43:30

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:45:09
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:43:30

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
Query 'hospital records = history of Squamous Cell Carcinoma on Elbow, 2020. Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:46:27
User opened query 'hospital records = history of Squamous Cell Carcinoma on Elbow, 2020. Please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:17:03
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 17:51:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:09:29

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:14:42
User closed query 'Per CDM: Please verify if this pertains to CHRONIC NEUROPATHIC PAIN' in Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding Medical History record. Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 20:42:20
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Peripheral neuropathic pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 07:19:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	06 Nov 2020 07:19:30
Data point term sent to Coder	System	26 Oct 2020 19:41:50
Query 'Per CDM: Please verify if this pertains to CHRONIC NEUROPATHIC PAIN' in Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding Medical History record. Please review and reconcile Con Med and MH as appropriate else clarify.' answered with 'Fields updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:41:40
User entered 'Chronic neuropathic pain- LEFT HAND' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:41:33
User opened query 'Per CDM: Please verify if this pertains to CHRONIC NEUROPATHIC PAIN' in Con Med eCRF? If yes, note that Con Med 'indication' does not match the corresponding Medical History record. Please review and reconcile Con Med and MH as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:11:41

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 09:10:04
Data point term sent to Coder	System	20 Oct 2020 21:34:01
DataPoint Un-verified.	Erica Osmundsen (b) (4)	20 Oct 2020 21:33:22
User entered 'PERIPHERAL NEUROPATHY LEFT HAND' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Oct 2020 21:33:22
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:10
Data point term sent to Coder	System	06 Oct 2020 01:03:56
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' answered with 'done' (Site from DM).	Erica Osmundsen (b) (4)	06 Oct 2020 01:03:45
Coding entries removed.	Erica Osmundsen (b) (4)	06 Oct 2020 01:03:33
User entered 'peripheral NEUROPATHY bilateral lower extremities' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	06 Oct 2020 01:03:33
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 12:39:44
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Neuropathy - version MedDRA\23.0.	Coder Import (b) (4)	17 Aug 2020 16:14:11

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Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	17 Aug 2020 16:14:11
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	17 Aug 2020 16:13:07
User entered 'Neuropathy'	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:01:31
User entered 'UN UNK 2015' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	20 Oct 2020 21:33:22
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:33
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:23
DataPoint Un-verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:13
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered 'UN UNK 2010'	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2015'	System	20 Oct 2020 21:33:22
User entered 'Jan 2010'	System	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2015'	System	20 Oct 2020 21:33:22
User entered '2010'	System	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	17 Aug 2020 16:12:01

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
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)	17 Aug 2020 16:15:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 16:15:14
Data point term sent to Coder	System	17 Aug 2020 16:14:17
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered 'UN UNK 2010'	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:41:10
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2010'	System	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2010'	System	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	17 Aug 2020 16:13:26

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:13
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Neuropathic pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:28:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:28:29
Data point term sent to Coder	System	20 Oct 2020 21:35:02
User entered 'CHRONIC NEUROPATHIC PAIN LEFT LEG'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:16
User entered 'UN UNK 2017'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:17
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:19
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:20
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:07:22
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2017'	System	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2017'	System	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:34:09

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:22
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal conditions NEC, HLT: Gastrointestinal mucosal dystrophies and secretion disorders, PT: Barrett's oesophagus, LLT: Barrett's esophagus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:36:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:36:29
Data point term sent to Coder	System	20 Oct 2020 21:35:05
User entered 'BARRETT'S ESOPHAGUS'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:24
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:26
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:29
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:10:36
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2012'	System	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2012'	System	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:34:46

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:47
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)	20 Oct 2020 21:37:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:32
Data point term sent to Coder	System	20 Oct 2020 21:36:07
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:48
User entered 'UN UNK 2010'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:50
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:52
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:53
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:11:55
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2010'	System	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2010'	System	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:08

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:09
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)	20 Oct 2020 21:37:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:32
Data point term sent to Coder	System	20 Oct 2020 21:36:08
User entered 'SLEEP APNEA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:11
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:13
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:15
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:17
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:18
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2012'	System	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2012'	System	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:31

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:45
User coded data point as SOC: Psychiatric disorders, HLTG: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 21:37:31
Data point term sent to Coder	System	20 Oct 2020 21:36:08
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:47
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:48
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:52
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:12:53
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2012'	System	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2012'	System	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:38

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:04
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Purine and pyrimidine metabolism disorders, HLT: Disorders of purine metabolism, PT: Gout, LLT: Gout - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:31
Data point term sent to Coder	System	20 Oct 2020 21:36:08
User entered 'GOUT'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:06
User entered 'UN UNK 2005'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:07
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:09
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:10
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:12
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2005'	System	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2005'	System	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:35:51

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:23
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Arrhythmia, LLT: Cardiac arrhythmia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:37:31
Data point term sent to Coder	System	20 Oct 2020 21:36:09
User entered 'CARDIAC ARRHYTHMIA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:24
User entered 'UN UNK 2018'	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:26
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:29
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:13:31
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2018'	System	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2018'	System	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	20 Oct 2020 21:36:03

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Pain knee - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:01:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Dec 2020 14:01:16
Data point term sent to Coder	System	09 Dec 2020 21:07:37
User entered 'CHRONIC PAIN RIGHT KNEE'	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:12:46
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 16:01:59
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 16:01:59
User entered 'UN UNK 2019' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 16:01:59
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:04
User entered 'UN Apr 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:06
User entered '0'	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:08
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:12
User entered empty.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:18:13
User entered '0'	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2019'	System	16 Apr 2021 16:01:59
User entered 'Apr 2020'	System	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2019'	System	16 Apr 2021 16:01:59
User entered '2020'	System	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	09 Dec 2020 21:07:28
DataPoint activated with code reason code Data required.	Erica Osmundsen (b) (4)	09 Dec 2020 21:07:03
DataPoint inactivated with code reason code Data not required.	Erica Osmundsen (b) (4)	20 Oct 2020 21:36:38

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:58:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Dec 2020 22:58:01
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:19:14
Data point term sent to Coder	System	09 Dec 2020 21:08:39
User entered 'RIGHT KNEE TORN MENISCUS REPAIR SURGERY'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:19:16
User entered 'UN Apr 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:19:19
User entered '0'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:19:22
User entered 'No (N)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:19:32
User entered 'UN Apr 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:19:28
User entered '0'	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Apr 2020'	System	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2020'	System	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Apr 2020'	System	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2020'	System	09 Dec 2020 21:08:05

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:12:56
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Allergy to nuts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:04:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:04:43
Data point term sent to Coder	System	16 Apr 2021 15:57:23
User entered 'allergy to brazil nuts'	Erica Osmundsen (b) (4) (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:12:58
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:00
User entered 'I'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:02
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:04
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:06
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:17

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:10
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergy to antibiotic - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:59:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:59:48
Data point term sent to Coder	System	16 Apr 2021 15:58:32
User entered 'ALLERGY TO DOXYCYCLINE'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:13:18
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:36
User entered 'I'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:38
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:40
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:42
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:57:55

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:47
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.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:00:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:00:49
Data point term sent to Coder	System	16 Apr 2021 15:59:34
User entered 'SCIATICA'	Erica Osmundsen (b) (4) 	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:51
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:52
User entered 'I'	Erica Osmundsen (b) (4)	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:54
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:56
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:15:58
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 15:59:27

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:05:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:05:46
Data point term sent to Coder	System	16 Apr 2021 16:04:41
User entered 'OSTEOARTHRITIS RIGHT KNEE'	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:05
User entered 'UN UNK 2019'	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:06
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:10
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:13
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:16:14
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Jan 2019'	System	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2019'	System	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered empty.	System	16 Apr 2021 16:03:53

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 10:08:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 10:08:29
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:46:08
Data point term sent to Coder	System	19 Apr 2021 18:03:12
User entered 'squamous cell skin cancer right elbow'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:46:10
User entered 'un Feb 2020'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:46:12
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:46:14
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:46:16
User entered 'un Aug 2020'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:46:18
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Feb 2020'	System	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2020'	System	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'Aug 2020'	System	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:43:30

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '2020'	System	19 Apr 2021 18:02:39

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:46:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:46:02
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:46:05
User entered '09:31'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '17 Aug 2020 09:31'	System	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:18:32
User closed query 'Height and weight should be noted for screening visit vitals. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:45:29
Query 'Height and weight should be noted for screening visit vitals. ' answered by data change (Site from CRA).	System	26 Oct 2020 19:40:29
User entered '168.4' cm reason for change: Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User opened query 'Height and weight should be noted for screening visit vitals. ' (Site from CRA).	(b) (4), (b) (6)	14 Oct 2020 18:48:49
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 08:58:56
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:26
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '168.4' cm	(b) (4), (b) (6)	17 Aug 2020 16:14:53
DataPoint set to visible.	System	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:18:38
User closed query 'Height and weight should be noted for screening visit vitals. ' (Site from CRA).	(b) (4), (b) (6)	17 Nov 2020 20:45:38
Query 'Height and weight should be noted for screening visit vitals. ' answered by data change (Site from CRA).	System	26 Oct 2020 19:40:29
User entered '89.6' kg reason for change: Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User opened query 'Height and weight should be noted for screening visit vitals. ' (Site from CRA).	(b) (4)	14 Oct 2020 18:49:11
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 08:59:04
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:28
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:59
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '89.6' kg	(b) (4), (b) (6)	17 Aug 2020 16:14:53
DataPoint set to visible.	System	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered '31.59540'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered '31.6'	System	17 Aug 2020 16:14:53
DataPoint set to visible.	System	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'kg/m2'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered 'kg/m2'	System	17 Aug 2020 16:14:53
DataPoint set to visible.	System	17 Aug 2020 13:54:13

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:18:54
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 08:59:06
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:30
User opened query 'Data is required. Please provide.' System (Site from System).		17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '37.0' C	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:18:56
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 08:59:20
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:32
User opened query 'Data is required. Please provide.' (Site from System).	System	17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:02
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 08:59:47
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:34
User opened query 'Data is required. Please provide.' System (Site from System).		17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '64'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'bpm'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered 'bpm'	System	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 09:00:02
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:36
User opened query 'Data is required. Please provide.' System (Site from System).		17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '18'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'breaths/min'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered 'breaths/min'	System	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	26 Oct 2020 19:40:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	18 Aug 2020 09:00:10
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:39
User opened query 'Data is required. Please provide.' System (Site from System).		17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '121'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'mmHg'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered 'mmHg'	System	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:12
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4)	26 Oct 2020 19:40:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	18 Aug 2020 09:00:13
Query 'Data is required. Please provide.' answered with 'Not done' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:17:41
User opened query 'Data is required. Please provide.' System (Site from System).		17 Aug 2020 16:16:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Aug 2020 16:16:45
User entered '76'	(b) (4), (b) (6)	17 Aug 2020 16:14:53

US3202217

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User entered 'mmHg'	System	26 Oct 2020 19:40:29
User entered empty.	System	17 Aug 2020 16:16:45
User entered 'mmHg'	System	17 Aug 2020 16:14:53

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:15:14

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:34
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	22 Sep 2020 19:27:37
User opened query 'The Physical Examination Date isSystem prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		14 Sep 2020 16:10:24
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:15:14

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

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Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

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)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 16:15:56

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

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)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

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Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

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)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

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)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered '0'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered 'I'	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
User entered '0'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:43:30

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:14:28
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:39
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:15:56

US3202217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:50
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:26

US3202217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:50
User entered '17 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:26

US3202217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[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 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:49:50
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:26

US3202217

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'VISIT1'	System	17 Aug 2020 13:54:26

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered '17 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:39:44

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 04:56:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:56:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	17 Aug 2020 13:39:44
User entered '186494' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:39:44

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Aug 2020 13:39:44

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

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 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:18:00

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

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 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:18:00

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

[Severe obesity \(body mass index > or = 40kg/m2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:18:00

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:18:00

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:09
User entered 'No (N)'	(b) (4), (b) (6)	17 Aug 2020 16:18:00

US3202217

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:43:30

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:19:44
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:52:00
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:22:28
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:35:47

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:43
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:24
User entered '168.4' cm	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:46
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:32
User entered '89.6' kg	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:43
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:24
User entered '168.4' cm	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:46
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:32
User entered '89.6' kg	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '09:31'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered '17 Aug 2020 09:31'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '37.0' C	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '64'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'bpm'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '18'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'breaths/min'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '121'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'mmHg'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '76'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'mmHg'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:43
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:03
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:24
User entered '168.4' cm	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 08:45:46
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'Field updated' (Site from DM).	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:32:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	12 Sep 2020 19:31:57
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 14:41:32
User entered '89.6' kg	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '17 Aug 2020'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 04:56:38
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 16:20:27
User entered '10:48'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered '17 Aug 2020 10:48'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '36.9' C	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered empty.	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '69'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'bpm'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '12'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'breaths/min'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '132'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'mmHg'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:50:26
User entered '78'	(b) (4), (b) (6)	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'mmHg'	System	17 Aug 2020 16:20:27

US3202217

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:12
User entered 'No (N)' reason for change: Data Entry Error	zackery harmon (b) (4)	29 Aug 2020 14:41:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:20:38

US3202217

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:12
User entered empty; reason for change Data Entry Error	zackery harmon (b) (4)	29 Aug 2020 14:41:32
User entered '17 Aug 2020'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 16:20:38

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

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 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'MRNA-1273 OR PLACEBO'	System	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered '17 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered '10:11'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered '17 Aug 2020 10:11'	System	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
DataPoint Verified.	(b) (4), (b) (6)	14 Oct 2020 18:56:24
User entered 'ONCE'	System	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'INTRAMUSCULAR'	System	17 Aug 2020 14:22:29

US3202217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:04
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:51

US3202217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:04
User entered '17 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:51

US3202217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:04
User entered '09:41'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:54:51

US3202217

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered '17 Aug 2020 09:41'	System	17 Aug 2020 13:54:51

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:43:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:12
User entered '17 Aug 2020'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:12
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:12
User entered '09:39'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered '17 Aug 2020 09:39'	System	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:12
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 13:55:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 13:55:12
User entered 'No (N)' reason for change: Data Entry Error	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:12
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 13:55:07
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:12
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered empty.	System	17 Aug 2020 13:55:07

US3202217

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 18:59:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Aug 2020 16:20:46

US3202217

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'I'	System	17 Aug 2020 16:20:46

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '34118ad3-9e8a-4d8b-8f83-663673c4aacf' User entered 'Yes (Y)'	System	17 Aug 2020 14:45:50
	System	17 Aug 2020 14:45:50

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:32', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '34118ad3-9e8a-4d8b-8f83-663673c4aacf' User entered '98.5'	System	17 Aug 2020 14:45:50
	System	17 Aug 2020 14:45:50

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:38', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '34118ad3-9e8a-4d8b-8f83-663673c4aacf'	System	17 Aug 2020 14:45:50
User entered 'No (N)'	System	17 Aug 2020 14:45:50

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:45', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '34118ad3-9e8a-4d8b-8f83-663673c4aacf' User entered '17 Aug 2020 10:45'	System	17 Aug 2020 14:45:50
	System	17 Aug 2020 14:45:50

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 10:31'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:10', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8b5582ec-0a64-4169-b225-9815755b44ab' User entered 'Yes (Y)'	System	18 Aug 2020 01:53:31
	System	18 Aug 2020 01:53:31

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8b5582ec-0a64-4169-b225-9815755b44ab' User entered '98.5'	System	18 Aug 2020 01:53:31
	System	18 Aug 2020 01:53:31

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8b5582ec-0a64-4169-b225-9815755b44ab'	System	18 Aug 2020 01:53:31
User entered 'No (N)'	System	18 Aug 2020 01:53:31

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8b5582ec-0a64-4169-b225-9815755b44ab'	System	18 Aug 2020 01:53:31
User entered '17 Aug 2020 21:53'	System	18 Aug 2020 01:53:31

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 2'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8d527624-3700-4272-8fc9-a8b064921a7a' User entered 'Yes (Y)'	System	19 Aug 2020 01:13:20
	System	19 Aug 2020 01:13:20

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:12:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8d527624-3700-4272-8fc9-a8b064921a7a' User entered '98.2'	System	19 Aug 2020 01:13:20
	System	19 Aug 2020 01:13:20

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8d527624-3700-4272-8fc9-a8b064921a7a'	System	19 Aug 2020 01:13:20
User entered 'No (N)'	System	19 Aug 2020 01:13:20

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:16', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8d527624-3700-4272-8fc9-a8b064921a7a'	System	19 Aug 2020 01:13:20
User entered '18 Aug 2020 21:13'	System	19 Aug 2020 01:13:20

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 3'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'faf868d9-05c6-4438-9099-ac36b14428fe' User entered 'Yes (Y)'	System	20 Aug 2020 02:01:22
	System	20 Aug 2020 02:01:22

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:10', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'faf868d9-05c6-4438-9099-ac36b14428fe' User entered '98.2'	System	20 Aug 2020 02:01:22
	System	20 Aug 2020 02:01:22

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'faf868d9-05c6-4438-9099-ac36b14428fe'	System	20 Aug 2020 02:01:22
User entered 'No (N)'	System	20 Aug 2020 02:01:22

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'faf868d9-05c6-4438-9099-ac36b14428fe' User entered '19 Aug 2020 22:01'	System	20 Aug 2020 02:01:22
	System	20 Aug 2020 02:01:22

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 4'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 5'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:07', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3c5fd6e1-b228-42d7-836d-4c1491477b54' User entered 'Yes (Y)'	System	21 Aug 2020 21:00:25
	System	21 Aug 2020 21:00:25

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3c5fd6e1-b228-42d7-836d-4c1491477b54' User entered '97.4'	System	21 Aug 2020 21:00:25
	System	21 Aug 2020 21:00:25

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:18', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3c5fd6e1-b228-42d7-836d-4c1491477b54'	System	21 Aug 2020 21:00:25
User entered 'No (N)'	System	21 Aug 2020 21:00:25

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3c5fd6e1-b228-42d7-836d-4c1491477b54'	System	21 Aug 2020 21:00:25
User entered '21 Aug 2020 17:00'	System	21 Aug 2020 21:00:25

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 6'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:32', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '806aafc7-74cf-4a64-bb44-394ad6e977c0' User entered 'Yes (Y)'	System	23 Aug 2020 00:23:53
	System	23 Aug 2020 00:23:53

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '806aafc7-74cf-4a64-bb44-394ad6e977c0' User entered '96.5'	System	23 Aug 2020 00:23:53
	System	23 Aug 2020 00:23:53

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:43', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '806aafc7-74cf-4a64-bb44-394ad6e977c0'	System	23 Aug 2020 00:23:53
User entered 'No (N)'	System	23 Aug 2020 00:23:53

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:48', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '806aafc7-74cf-4a64-bb44-394ad6e977c0'	System	23 Aug 2020 00:23:53
User entered '22 Aug 2020 20:23'	System	23 Aug 2020 00:23:53

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 7'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '302c8645-7555-4760-8252-09cfc5817c41'	System	24 Aug 2020 01:28:47
User entered 'Yes (Y)'	System	24 Aug 2020 01:28:47

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '302c8645-7555-4760-8252-09cfc5817c41' User entered '98.2'	System	24 Aug 2020 01:28:47
	System	24 Aug 2020 01:28:47

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '302c8645-7555-4760-8252-09cfc5817c41' User entered 'No (N)'	System	24 Aug 2020 01:28:47
	System	24 Aug 2020 01:28:47

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:44', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '302c8645-7555-4760-8252-09cfc5817c41'	System	24 Aug 2020 01:28:47
User entered '23 Aug 2020 21:28'	System	24 Aug 2020 01:28:47

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f99c0beb-c555-479f-84b4-32f688e658e8' User entered 'None (1)'	System	17 Aug 2020 14:46:36
	System	17 Aug 2020 14:46:36

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:45:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f99c0beb-c555-479f-84b4-32f688e658e8' User entered 'No (N)'	System	17 Aug 2020 14:46:36
	System	17 Aug 2020 14:46:36

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:46:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f99c0beb-c555-479f-84b4-32f688e658e8' User entered 'No (N)'	System	17 Aug 2020 14:46:36
	System	17 Aug 2020 14:46:36

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:46:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f99c0beb-c555-479f-84b4-32f688e658e8'	System	17 Aug 2020 14:46:36
User entered 'None (1)'	System	17 Aug 2020 14:46:36

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:46:17', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f99c0beb-c555-479f-84b4-32f688e658e8' User entered '17 Aug 2020 10:46'	System	17 Aug 2020 14:46:36
	System	17 Aug 2020 14:46:36

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 10:31'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:37', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f4a83e8e-19a2-409d-b696-470bee48cb28'	System	18 Aug 2020 01:54:11
User entered 'None (1)'	System	18 Aug 2020 01:54:11

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f4a83e8e-19a2-409d-b696-470bee48cb28'	System	18 Aug 2020 01:54:11
User entered 'No (N)'	System	18 Aug 2020 01:54:11

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:53:50', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f4a83e8e-19a2-409d-b696-470bee48cb28' User entered 'No (N)'	System	18 Aug 2020 01:54:11
	System	18 Aug 2020 01:54:11

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:01', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f4a83e8e-19a2-409d-b696-470bee48cb28'	System	18 Aug 2020 01:54:11
User entered 'None (1)'	System	18 Aug 2020 01:54:11

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f4a83e8e-19a2-409d-b696-470bee48cb28'	System	18 Aug 2020 01:54:11
User entered '17 Aug 2020 21:54'	System	18 Aug 2020 01:54:11

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 2'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5d142956-7719-4ec2-9cb7-546e34b2f9c9'	System	19 Aug 2020 01:13:38
User entered 'None (1)'	System	19 Aug 2020 01:13:38

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:25', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5d142956-7719-4ec2-9cb7-546e34b2f9c9'	System	19 Aug 2020 01:13:38
User entered 'No (N)'	System	19 Aug 2020 01:13:38

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:28', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5d142956-7719-4ec2-9cb7-546e34b2f9c9' User entered 'No (N)'	System	19 Aug 2020 01:13:38
	System	19 Aug 2020 01:13:38

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:31', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5d142956-7719-4ec2-9cb7-546e34b2f9c9'	System	19 Aug 2020 01:13:38
User entered 'None (1)'	System	19 Aug 2020 01:13:38

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5d142956-7719-4ec2-9cb7-546e34b2f9c9' User entered '18 Aug 2020 21:13'	System	19 Aug 2020 01:13:38
	System	19 Aug 2020 01:13:38

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 3'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:24', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '51dae3b8-1f22-420b-872b-259b0cf6300a' User entered 'None (1)'	System	20 Aug 2020 02:01:39
	System	20 Aug 2020 02:01:39

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:27', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '51dae3b8-1f22-420b-872b-259b0cf6300a' User entered 'No (N)'	System	20 Aug 2020 02:01:39
	System	20 Aug 2020 02:01:39

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '51dae3b8-1f22-420b-872b-259b0cf6300a' User entered 'No (N)'	System	20 Aug 2020 02:01:39
	System	20 Aug 2020 02:01:39

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '51dae3b8-1f22-420b-872b-259b0cf6300a'	System	20 Aug 2020 02:01:39
User entered 'None (1)'	System	20 Aug 2020 02:01:39

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:35', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '51dae3b8-1f22-420b-872b-259b0cf6300a' User entered '19 Aug 2020 22:01'	System	20 Aug 2020 02:01:39
	System	20 Aug 2020 02:01:39

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 4'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 5'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:26', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1486bd70-71ec-46c1-8d62-50f43e2f22bb' User entered 'None (1)'	System	21 Aug 2020 21:00:45
	System	21 Aug 2020 21:00:45

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1486bd70-71ec-46c1-8d62-50f43e2f22bb'	System	21 Aug 2020 21:00:45
User entered 'No (N)'	System	21 Aug 2020 21:00:45

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:32', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1486bd70-71ec-46c1-8d62-50f43e2f22bb'	System	21 Aug 2020 21:00:45
User entered 'No (N)'	System	21 Aug 2020 21:00:45

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1486bd70-71ec-46c1-8d62-50f43e2f22bb'	System	21 Aug 2020 21:00:45
User entered 'None (1)'	System	21 Aug 2020 21:00:45

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1486bd70-71ec-46c1-8d62-50f43e2f22bb'	System	21 Aug 2020 21:00:45
User entered '21 Aug 2020 17:00'	System	21 Aug 2020 21:00:45

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 6'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '492f6cf7-deb7-4317-b95c-7e9b71b78715'	System	23 Aug 2020 00:24:10
User entered 'None (1)'	System	23 Aug 2020 00:24:10

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '492f6cf7-deb7-4317-b95c-7e9b71b78715'	System	23 Aug 2020 00:24:10
User entered 'No (N)'	System	23 Aug 2020 00:24:10

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:23:58', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '492f6cf7-deb7-4317-b95c-7e9b71b78715'	System	23 Aug 2020 00:24:10
User entered 'No (N)'	System	23 Aug 2020 00:24:10

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '492f6cf7-deb7-4317-b95c-7e9b71b78715'	System	23 Aug 2020 00:24:10
User entered 'None (1)'	System	23 Aug 2020 00:24:10

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '492f6cf7-deb7-4317-b95c-7e9b71b78715'	System	23 Aug 2020 00:24:10
User entered '22 Aug 2020 20:24'	System	23 Aug 2020 00:24:10

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 7'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:49', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0997ba4f-1666-42d9-a30b-6dbbcd854245'	System	24 Aug 2020 01:30:08
User entered 'None (1)'	System	24 Aug 2020 01:30:08

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:52', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0997ba4f-1666-42d9-a30b-6dbbcd854245' User entered 'No (N)'	System	24 Aug 2020 01:30:08
	System	24 Aug 2020 01:30:08

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:28:54', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0997ba4f-1666-42d9-a30b-6dbbcd854245' User entered 'No (N)'	System	24 Aug 2020 01:30:08
	System	24 Aug 2020 01:30:08

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0997ba4f-1666-42d9-a30b-6dbbcd854245'	System	24 Aug 2020 01:30:08
User entered 'None (1)'	System	24 Aug 2020 01:30:08

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:14', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0997ba4f-1666-42d9-a30b-6dbbcd854245'	System	24 Aug 2020 01:30:08
User entered '23 Aug 2020 21:29'	System	24 Aug 2020 01:30:08

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:46:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:46:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:10', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'None (0)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:16', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered 'No (N)'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T10:47:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '01fb5838-03d5-4beb-837e-d76e480c670f' User entered '17 Aug 2020 10:47'	System	17 Aug 2020 14:47:24
	System	17 Aug 2020 14:47:24

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 10:31'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 1, after vaccination (at home)'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:14', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83'	System	18 Aug 2020 01:54:37
User entered 'None (0)'	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:17', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83' User entered 'None (0)'	System	18 Aug 2020 01:54:37
	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:20', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83' User entered 'None (0)'	System	18 Aug 2020 01:54:37
	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83' User entered 'None (0)'	System	18 Aug 2020 01:54:37
	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:26', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83' User entered 'None (0)'	System	18 Aug 2020 01:54:37
	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83' User entered 'None (0)'	System	18 Aug 2020 01:54:37
	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83'	System	18 Aug 2020 01:54:37
User entered 'No (N)'	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-17T21:54:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9a8f9404-d930-407b-8191-d364e3df0a83'	System	18 Aug 2020 01:54:37
User entered '17 Aug 2020 21:54'	System	18 Aug 2020 01:54:37

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Aug 2020 13:56'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 2'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:45', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:48', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:51', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:13:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'None (0)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:14:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered 'Yes (Y)'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-18T21:14:14', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '68dbee42-d7e7-4a15-b7dd-85a38c94306d' User entered '18 Aug 2020 21:14'	System	19 Aug 2020 01:14:16
	System	19 Aug 2020 01:14:16

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 3'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:45', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:47', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:54', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:01:57', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:02:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'None (0)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:02:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered 'No (N)'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-19T22:02:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '031c97c2-ab0e-4d9f-9149-0ec507bc7a7a' User entered '19 Aug 2020 22:02'	System	20 Aug 2020 02:02:08
	System	20 Aug 2020 02:02:08

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 4'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 5'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:47', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:51', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:54', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:00:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:01:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'None (0)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:01:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered 'No (N)'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-21T17:01:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74295c6e-8af7-4797-9272-51c5de8dcef8' User entered '21 Aug 2020 17:01'	System	21 Aug 2020 21:01:11
	System	21 Aug 2020 21:01:11

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 6'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883' User entered 'None (0)'	System	23 Aug 2020 00:24:46
	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:20', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883'	System	23 Aug 2020 00:24:46
User entered 'No interference with activity (1)'	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883' User entered 'None (0)'	System	23 Aug 2020 00:24:46
	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:28', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883' User entered 'None (0)'	System	23 Aug 2020 00:24:46
	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:32', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883' User entered 'None (0)'	System	23 Aug 2020 00:24:46
	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883' User entered 'None (0)'	System	23 Aug 2020 00:24:46
	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:39', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883'	System	23 Aug 2020 00:24:46
User entered 'No (N)'	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-22T20:24:41', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9f38f350-3557-44bd-b47f-996ca231c883'	System	23 Aug 2020 00:24:46
User entered '22 Aug 2020 20:24'	System	23 Aug 2020 00:24:46

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '22 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 7'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:20', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:26', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:31', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:34', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'None (0)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:38', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered 'No (N)'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-08-23T21:29:41', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '10e38e73-5416-428f-b5c1-c457aec979ae' User entered '23 Aug 2020 21:29'	System	24 Aug 2020 01:30:22
	System	24 Aug 2020 01:30:22

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '23 Aug 2020 12:00'	System	17 Aug 2020 14:22:29

US3202217

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '24 Aug 2020 11:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:23:37
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:37:10

US3202217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:23:37
User entered '27 Aug 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:37:10

US3202217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:23:37
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:37:10

US3202217

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:23:37
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:37:10

US3202217

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:23:55
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:09:37

US3202217

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'I'	System	14 Sep 2020 16:09:37

US3202217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:26:49
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:38:44

US3202217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:26:49
User entered '2 Sep 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:38:44

US3202217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:26:49
User entered 'Contact Not Made (CONTACT NOT MADE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:38:44

US3202217

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:26:49
User entered 'UNABLE TO REACH'	Erica Osmundsen (b) (4)	20 Oct 2020 21:38:44

US3202217

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:27:08
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:07

US3202217

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 13:00:58
User entered 'I'	System	14 Sep 2020 16:10:07

US3202217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:28:12
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:39:27

US3202217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:28:12
User entered '8 Sep 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:39:27

US3202217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:28:12
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:39:27

US3202217

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:28:12
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:39:27

US3202217

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:28:20
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:15

US3202217

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:59:15
User entered 'I'	System	14 Sep 2020 16:10:15

US3202217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:26:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 11:30:54
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'UPDATED IN EDC NOW' (Site from DM).	Erica Osmundsen (b) (4)	09 Dec 2020 21:30:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 13:04:10
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:24

US3202217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:35:36
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:24

US3202217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:35:38
User entered 'Clinic (Clinic)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:24

US3202217

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'VISIT2'	System	14 Sep 2020 16:10:24

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User accepted default value 'Pre-Dose (PREDOSE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '14 Sep 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '11:14'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '14 Sep 2020 11:14'	System	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '37.0' C	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered 'Oral (Oral)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '77'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'bpm'	System	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '14'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'breaths/min'	System	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '142'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '87'	Erica Osmundsen (b) (4)	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	20 Oct 2020 21:40:26

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User accepted default value 'Post-Dose (POSTDOSE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '14 Sep 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '12:31'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '14 Sep 2020 12:31'	System	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '37.1' C	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered 'Oral (Oral)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '71'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'bpm'	System	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '12'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'breaths/min'	System	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '141'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:37:26
User entered '90'	Erica Osmundsen (b) (4)	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	20 Oct 2020 21:41:11

US3202217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:00
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:30

US3202217

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:00
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:30

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'MRNA-1273 OR PLACEBO'	System	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered '11:57'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '14 Sep 2020 11:57'	System	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered 'Left Arm (LEFT ARM)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:38:54
User entered 'ONCE'	System	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'INTRAMUSCULAR'	System	14 Sep 2020 16:10:53

US3202217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:09
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:11:57

US3202217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:09
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:11:57

US3202217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:09
User entered '11:23'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:11:57

US3202217

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '14 Sep 2020 11:23'	System	14 Sep 2020 16:11:57

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:19
User entered '14 Sep 2020'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tiffany Jewell (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:19
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:19
User entered '11:21'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '14 Sep 2020 11:21'	System	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tiffany Jewell (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:19
User entered 'No (N)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:19
User entered empty.	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered empty.	System	14 Sep 2020 16:12:36

US3202217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:39:31
User entered 'Yes (Y)'	Tiffany Jewell (b) (4) (b) (4)	14 Sep 2020 16:11:01

US3202217

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '1'	System	14 Sep 2020 16:11:01

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:28', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered 'Yes (Y)'	System	14 Sep 2020 17:02:17
	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:39', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered '98.6'	System	14 Sep 2020 17:02:17
	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:46', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d'	System	14 Sep 2020 17:02:17
User entered 'Yes (Y)'	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contact made. Medication taken was for chronic pain. Not vaccine related' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:49:09
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered '1'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:14:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	14 Sep 2020 17:02:17
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered '1'	System	14 Sep 2020 17:02:17
User entered '1'	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:00:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered '0'	System	14 Sep 2020 17:02:17
	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:01:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '44603652-2b7b-4f80-8046-2004b03d7d2d' User entered '14 Sep 2020 13:01'	System	14 Sep 2020 17:02:17
	System	14 Sep 2020 17:02:17

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 12:17'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 14:47'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:40:54', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	System	14 Sep 2020 21:41:21
User entered 'Yes (Y)'	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:04', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	System	14 Sep 2020 21:41:21
User entered '97.6'	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	System	14 Sep 2020 21:41:21
User entered 'Yes (Y)'	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'medication taken was for chronic pain not vaccine related' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:49:52
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Lilian Nukuna (b) (4)	21 Sep 2020 15:15:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	(b) (4)	
User entered '1'	System	14 Sep 2020 21:41:21
	System	14 Sep 2020 21:41:21
	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	System	14 Sep 2020 21:41:21
User entered '0'	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:17', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3f944f9e-57bd-41be-84cf-fc3356cebe57'	System	14 Sep 2020 21:41:21
User entered '14 Sep 2020 17:41'	System	14 Sep 2020 21:41:21

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 15:42'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 2'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:39', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd' User entered 'Yes (Y)'	System	15 Sep 2020 20:52:07
	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:50', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd' User entered '98.3'	System	15 Sep 2020 20:52:07
	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd'	System	15 Sep 2020 20:52:07
User entered 'Yes (Y)'	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'contact made. medication taken was for chronic pain. Not vaccine related' (Site from System).	(b) (4), (b) (6)	22 Oct 2020 11:56:01
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd' User entered '1'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:15:55
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	15 Sep 2020 20:52:07
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd' User entered '1'	System	15 Sep 2020 20:52:07
User entered '1'	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:51:59', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd' User entered '0'	System	15 Sep 2020 20:52:07
	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '78e94641-3ea9-469c-ab38-b60dcc91f9dd'	System	15 Sep 2020 20:52:07
User entered '15 Sep 2020 16:52'	System	15 Sep 2020 20:52:07

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 3'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 4'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '7a8a5422-b59e-41ec-9de8-14c85fe60d0a' User entered 'No (N)'	System	17 Sep 2020 22:00:42
	System	17 Sep 2020 22:00:42

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '7a8a5422-b59e-41ec-9de8-14c85fe60d0a' User entered 'No (N)'	System	17 Sep 2020 22:00:42
	System	17 Sep 2020 22:00:42

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:41', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '7a8a5422-b59e-41ec-9de8-14c85fe60d0a' User entered '17 Sep 2020 18:00'	System	17 Sep 2020 22:00:42
	System	17 Sep 2020 22:00:42

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 5'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '15e02fa7-2d53-4d80-bfd7-aa45cdbb6d83' User entered 'No (N)'	System	19 Sep 2020 02:39:40
	System	19 Sep 2020 02:39:40

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:44', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '15e02fa7-2d53-4d80-bfd7-aa45cdbb6d83'	System	19 Sep 2020 02:39:40
User entered 'No (N)'	System	19 Sep 2020 02:39:40

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:47', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '15e02fa7-2d53-4d80-bfd7-aa45cdbb6d83' User entered '18 Sep 2020 22:35'	System	19 Sep 2020 02:39:40
	System	19 Sep 2020 02:39:40

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 6'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 7'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:47', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e45bc18e-5b7b-470b-8098-6ff80f8e851a' User entered 'No (N)'	System	20 Sep 2020 23:54:56
	System	20 Sep 2020 23:54:56

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:50', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e45bc18e-5b7b-470b-8098-6ff80f8e851a'	System	20 Sep 2020 23:54:56
User entered 'No (N)'	System	20 Sep 2020 23:54:56

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e45bc18e-5b7b-470b-8098-6ff80f8e851a' User entered '20 Sep 2020 19:54'	System	20 Sep 2020 23:54:56
	System	20 Sep 2020 23:54:56

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:02:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '4ceb1e0f-7666-4d93-9f90-c0028efe77c1' User entered 'None (1)'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:02:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '4ceb1e0f-7666-4d93-9f90-c0028efe77c1' User entered 'No (N)'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:02:49', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '4ceb1e0f-7666-4d93-9f90-c0028efe77c1' User entered 'No (N)'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:02:52', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '4ceb1e0f-7666-4d93-9f90-c0028efe77c1' User entered 'None (1)'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '4ceb1e0f-7666-4d93-9f90-c0028efe77c1' User entered '14 Sep 2020 13:03'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 12:17'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 14:47'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:41:31', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2e017299-86b2-419b-b4b3-cb85026d6fcf'	System	14 Sep 2020 21:42:38
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 21:42:38

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2e017299-86b2-419b-b4b3-cb85026d6fcf' User entered 'No (N)'	System	14 Sep 2020 21:42:38
	System	14 Sep 2020 21:42:38

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:25', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2e017299-86b2-419b-b4b3-cb85026d6fcf' User entered 'No (N)'	System	14 Sep 2020 21:42:38
	System	14 Sep 2020 21:42:38

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2e017299-86b2-419b-b4b3-cb85026d6fcf'	System	14 Sep 2020 21:42:38
User entered 'None (1)'	System	14 Sep 2020 21:42:38

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2e017299-86b2-419b-b4b3-cb85026d6fcf' User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:42:38
	System	14 Sep 2020 21:42:38

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 15:42'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 2'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '57d2c0e6-a8dc-401c-8899-49d0f870e94d' User entered 'None (1)'	System	15 Sep 2020 20:52:27
	System	15 Sep 2020 20:52:27

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:16', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '57d2c0e6-a8dc-401c-8899-49d0f870e94d' User entered 'No (N)'	System	15 Sep 2020 20:52:27
	System	15 Sep 2020 20:52:27

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:18', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '57d2c0e6-a8dc-401c-8899-49d0f870e94d' User entered 'No (N)'	System	15 Sep 2020 20:52:27
	System	15 Sep 2020 20:52:27

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:21', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '57d2c0e6-a8dc-401c-8899-49d0f870e94d' User entered 'None (1)'	System	15 Sep 2020 20:52:27
	System	15 Sep 2020 20:52:27

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:25', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '57d2c0e6-a8dc-401c-8899-49d0f870e94d' User entered '15 Sep 2020 16:52'	System	15 Sep 2020 20:52:27
	System	15 Sep 2020 20:52:27

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 3'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 4'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:46', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1e7c0ebc-1c67-43d0-a8ad-1ac1357c278e' User entered 'None (1)'	System	17 Sep 2020 22:01:06
	System	17 Sep 2020 22:01:06

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:50', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1e7c0ebc-1c67-43d0-a8ad-1ac1357c278e' User entered 'No (N)'	System	17 Sep 2020 22:01:06
	System	17 Sep 2020 22:01:06

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:53', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1e7c0ebc-1c67-43d0-a8ad-1ac1357c278e' User entered 'No (N)'	System	17 Sep 2020 22:01:06
	System	17 Sep 2020 22:01:06

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:00:55', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1e7c0ebc-1c67-43d0-a8ad-1ac1357c278e' User entered 'None (1)'	System	17 Sep 2020 22:01:06
	System	17 Sep 2020 22:01:06

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:01', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1e7c0ebc-1c67-43d0-a8ad-1ac1357c278e' User entered '17 Sep 2020 18:01'	System	17 Sep 2020 22:01:06
	System	17 Sep 2020 22:01:06

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 5'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:52', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '75971562-33fe-4e4c-ba7b-49ea6d59cdfb'	System	19 Sep 2020 02:39:45
User entered 'None (1)'	System	19 Sep 2020 02:39:45

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:55', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '75971562-33fe-4e4c-ba7b-49ea6d59cdfb' User entered 'No (N)'	System	19 Sep 2020 02:39:45
	System	19 Sep 2020 02:39:45

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:35:58', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '75971562-33fe-4e4c-ba7b-49ea6d59cdfb'	System	19 Sep 2020 02:39:45
User entered 'No (N)'	System	19 Sep 2020 02:39:45

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:01', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '75971562-33fe-4e4c-ba7b-49ea6d59cdfb'	System	19 Sep 2020 02:39:45
User entered 'None (1)'	System	19 Sep 2020 02:39:45

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:04', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '75971562-33fe-4e4c-ba7b-49ea6d59cdfb' User entered '18 Sep 2020 22:36'	System	19 Sep 2020 02:39:45
	System	19 Sep 2020 02:39:45

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 6'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 7'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:28', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4cb7207-ae85-4e75-b590-0739c3a43460' User entered 'None (1)'	System	20 Sep 2020 23:54:43
	System	20 Sep 2020 23:54:43

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:31', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4cb7207-ae85-4e75-b590-0739c3a43460' User entered 'No (N)'	System	20 Sep 2020 23:54:43
	System	20 Sep 2020 23:54:43

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4cb7207-ae85-4e75-b590-0739c3a43460'	System	20 Sep 2020 23:54:43
User entered 'No (N)'	System	20 Sep 2020 23:54:43

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4cb7207-ae85-4e75-b590-0739c3a43460' User entered 'None (1)'	System	20 Sep 2020 23:54:43
	System	20 Sep 2020 23:54:43

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4cb7207-ae85-4e75-b590-0739c3a43460' User entered '20 Sep 2020 19:54'	System	20 Sep 2020 23:54:43
	System	20 Sep 2020 23:54:43

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:12', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:18', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:27', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'None (0)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:32', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered 'No (N)'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T13:03:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '733080bc-f54a-4688-b43b-fa4990cc3e61' User entered '14 Sep 2020 13:03'	System	14 Sep 2020 17:04:54
	System	14 Sep 2020 17:04:54

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 12:17'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 14:47'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 1, after vaccination (at home)'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:38', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:44', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:47', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:49', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:52', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'None (0)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered 'No (N)'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-14T17:42:58', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '48ea43a3-036b-4dbf-ab8a-d0099a52b9b9' User entered '14 Sep 2020 17:42'	System	14 Sep 2020 21:43:03
	System	14 Sep 2020 21:43:03

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '14 Sep 2020 15:42'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 2'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:31', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:34', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:37', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:41', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:43', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:46', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'None (0)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:49', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered 'No (N)'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-15T16:52:51', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'ba9a0427-26d9-4f15-9fa0-9a2f439e2e3c' User entered '15 Sep 2020 16:52'	System	15 Sep 2020 20:52:53
	System	15 Sep 2020 20:52:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '15 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 3'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '16 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 4'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:06', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:17', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'None (0)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:23', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered 'No (N)'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-17T18:01:26', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b604d49-7b21-4abb-b6b8-807bd67bd1e1' User entered '17 Sep 2020 18:01'	System	17 Sep 2020 22:01:27
	System	17 Sep 2020 22:01:27

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '17 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 5'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:14', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:17', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'None (0)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8' User entered 'No (N)'	System	19 Sep 2020 02:39:49
	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-18T22:36:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '90c54709-7202-4375-a90d-1e1ea373fbd8'	System	19 Sep 2020 02:39:49
User entered '18 Sep 2020 22:36'	System	19 Sep 2020 02:39:49

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '18 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 6'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '19 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	14 Sep 2020 16:10:53
User entered 'Day 7'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:54:58', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:02', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:04', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:07', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'None (0)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered 'No (N)'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-09-20T19:55:16', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '871264aa-a827-415a-9ae1-678b56782148' User entered '20 Sep 2020 19:55'	System	20 Sep 2020 23:55:19
	System	20 Sep 2020 23:55:19

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '20 Sep 2020 12:00'	System	14 Sep 2020 16:10:53

US3202217

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:43:30

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
User entered '21 Sep 2020 11:59'	System	14 Sep 2020 16:10:53

US3202217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:29:06
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:13:47

US3202217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:29:06
User entered '21 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:13:47

US3202217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:29:06
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:13:47

US3202217

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:29:06
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:13:47

US3202217

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:29:23
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	21 Sep 2020 15:14:13

US3202217

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'I'	System	21 Sep 2020 15:14:13

US3202217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:30:59
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 09:12:46
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'EDC UPDATED' (Site from DM).	Erica Osmundsen (b) (4)	09 Dec 2020 21:30:23
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 13OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 11:37:11
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 19:59:11

US3202217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:33:33
User entered '28 Sep 2020'	Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 19:59:11

US3202217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:33:36
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 19:59:11

US3202217

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:33:38
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 19:59:11

US3202217

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:33:51
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	28 Sep 2020 19:59:16

US3202217

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'I'	System	28 Sep 2020 19:59:16

US3202217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:34:05
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:42:13

US3202217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:34:05
User entered '5 Oct 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:42:13

US3202217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:34:05
User entered 'Contact Made (CONTACT MADE)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:42:13

US3202217

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:34:05
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:42:13

US3202217

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:25
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:34:24
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:42:19

US3202217

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'I'	System	20 Oct 2020 21:42:19

US3202217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:36:32
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:27:50

US3202217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:36:32
User entered '13 Oct 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:27:50

US3202217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:36:32
User entered 'Clinic (Clinic)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:27:50

US3202217

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'VISIT3'	System	09 Dec 2020 21:27:50

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '13 Oct 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '08:19'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '13 Oct 2020 08:19'	System	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '36.9' C	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered 'Oral (Oral)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered empty.	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '67'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'bpm'	System	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '12'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'breaths/min'	System	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '148'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:11
User entered '81'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'mmHg'	System	09 Dec 2020 21:28:23

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25

US3202217

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25

US3202217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:29
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:44

US3202217

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:37:29
User entered '13 Oct 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:28:44

US3202217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:47:28
Query 'please confirm as there is no source for lab collection at this visit' canceled (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 18:47:19
User opened query 'please confirm as there is no source for lab collection at this visit' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 17:39:33
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	09 Dec 2020 21:29:48

US3202217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:47:28
User entered '13 Oct 2020'	Erica Osmundsen (b) (4)	09 Dec 2020 21:29:48

US3202217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 18:47:28
User entered '08:27'	Erica Osmundsen (b) (4)	09 Dec 2020 21:29:48

US3202217

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '13 Oct 2020 08:27'	System	09 Dec 2020 21:29:48

US3202217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:43:45
User signature succeeded.	Mark McKenzie (b) (4)	13 Feb 2021 02:13:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:30:45

US3202217

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered '1'	System	10 Nov 2020 19:30:45

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 64'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-10-19T22:01:18', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '678cedcc-5d82-4c46-abf6-bf6a61864bfd'	System	20 Oct 2020 02:01:40
User entered 'No (N)'	System	20 Oct 2020 02:01:40

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-10-19T22:01:26', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '678cedcc-5d82-4c46-abf6-bf6a61864bfd'	System	20 Oct 2020 02:01:40
User entered 'No (N)'	System	20 Oct 2020 02:01:40

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-10-19T22:01:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '678cedcc-5d82-4c46-abf6-bf6a61864bfd' User entered '19 Oct 2020 22:01:33'	System	20 Oct 2020 02:01:40
	System	20 Oct 2020 02:01:40

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '17 Oct 2020 00:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '21 Oct 2020 23:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 71'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '24 Oct 2020 00:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '28 Oct 2020 23:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 78'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '31 Oct 2020 00:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 08:56:49
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '04 Nov 2020 23:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered 'Day 92'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-14T08:11:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4c3bb6d-a161-4dd9-bd44-3c64bc87a3e7' User entered 'No (N)'	System	14 Nov 2020 13:11:45
	System	14 Nov 2020 13:11:45

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-14T08:11:36', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4c3bb6d-a161-4dd9-bd44-3c64bc87a3e7' User entered 'No (N)'	System	14 Nov 2020 13:11:45
	System	14 Nov 2020 13:11:45

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-14T08:11:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a4c3bb6d-a161-4dd9-bd44-3c64bc87a3e7' User entered '14 Nov 2020 08:11:42'	System	14 Nov 2020 13:11:45
	System	14 Nov 2020 13:11:45

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '14 Nov 2020 00:01'	System	17 Aug 2020 14:22:29

US3202217

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:38:23
Data entry locked.	System	17 Aug 2020 14:22:29
User entered '18 Nov 2020 23:59'	System	17 Aug 2020 14:22:29

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-21T13:30:04', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1ab97b01-17bb-4fbd-a544-b7356e8515e9' User entered 'No (N)'	System	21 Nov 2020 18:30:19
	System	21 Nov 2020 18:30:19

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-21T13:30:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1ab97b01-17bb-4fbd-a544-b7356e8515e9' User entered 'No (N)'	System	21 Nov 2020 18:30:19
	System	21 Nov 2020 18:30:19

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-21T13:30:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1ab97b01-17bb-4fbd-a544-b7356e8515e9' User entered '21 Nov 2020 13:30:15'	System	21 Nov 2020 18:30:19
	System	21 Nov 2020 18:30:19

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-26T16:14:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'd715be41-d2ca-458d-974f-305d51f9f0db' User entered 'No (N)'	System	26 Nov 2020 21:14:42
	System	26 Nov 2020 21:14:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-26T16:14:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'd715be41-d2ca-458d-974f-305d51f9f0db' User entered 'No (N)'	System	26 Nov 2020 21:14:42
	System	26 Nov 2020 21:14:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-11-26T16:14:37', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'd715be41-d2ca-458d-974f-305d51f9f0db' User entered '26 Nov 2020 16:14:37'	System	26 Nov 2020 21:14:42
	System	26 Nov 2020 21:14:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-02T21:42:30', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2fad8338-7ab2-43ec-a8a7-05070829fa05'	System	03 Dec 2020 02:42:39
User entered 'No (N)'	System	03 Dec 2020 02:42:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-02T21:42:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2fad8338-7ab2-43ec-a8a7-05070829fa05'	System	03 Dec 2020 02:42:39
User entered 'No (N)'	System	03 Dec 2020 02:42:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-02T21:42:38', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2fad8338-7ab2-43ec-a8a7-05070829fa05' User entered '02 Dec 2020 21:42:38'	System	03 Dec 2020 02:42:39
	System	03 Dec 2020 02:42:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-12T22:16:30', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'b4e4f2ae-021e-4592-a0e7-d9e34dd756e1' User entered 'No (N)'	System	13 Dec 2020 03:16:43
	System	13 Dec 2020 03:16:43

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-12T22:16:34', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'b4e4f2ae-021e-4592-a0e7-d9e34dd756e1' User entered 'No (N)'	System	13 Dec 2020 03:16:43
	System	13 Dec 2020 03:16:43

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-12T22:16:40', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'b4e4f2ae-021e-4592-a0e7-d9e34dd756e1' User entered '12 Dec 2020 22:16:40'	System	13 Dec 2020 03:16:43
	System	13 Dec 2020 03:16:43

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-19T12:21:42', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74bebcef-eedf-4687-8249-31fa03627393'	System	19 Dec 2020 17:21:53
User entered 'No (N)'	System	19 Dec 2020 17:21:53

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-19T12:21:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74bebcef-eedf-4687-8249-31fa03627393'	System	19 Dec 2020 17:21:53
User entered 'No (N)'	System	19 Dec 2020 17:21:53

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-19T12:21:51', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '74bebcef-eedf-4687-8249-31fa03627393' User entered '19 Dec 2020 12:21:51'	System	19 Dec 2020 17:21:53
	System	19 Dec 2020 17:21:53

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-27T22:41:35', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8ff78ba6-e1d3-4c5e-b1af-a2dd28f49dcb' User entered 'Yes (Y)'	System	08 Jan 2021 03:39:51
	System	08 Jan 2021 03:39:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-27T22:41:45', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8ff78ba6-e1d3-4c5e-b1af-a2dd28f49dcb' User entered 'No (N)'	System	08 Jan 2021 03:39:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-27T22:41:49', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8ff78ba6-e1d3-4c5e-b1af-a2dd28f49dcb' User entered 'No (N)'	System	08 Jan 2021 03:39:51
	System	08 Jan 2021 03:39:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-27T22:41:56', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8ff78ba6-e1d3-4c5e-b1af-a2dd28f49dcb' User entered 'No (N)'	System	08 Jan 2021 03:39:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2020-12-27T22:42:01', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '8ff78ba6-e1d3-4c5e-b1af-a2dd28f49dcb' User entered '27 Dec 2020 22:42:01'	System	08 Jan 2021 03:39:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-07T22:40:33', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'af8ca074-171f-4a6b-8257-52b7f2c3ed70'	System	08 Jan 2021 03:40:42
User entered 'No (N)'	System	08 Jan 2021 03:40:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-07T22:40:29', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'af8ca074-171f-4a6b-8257-52b7f2c3ed70'	System	08 Jan 2021 03:40:42
User entered 'No (N)'	System	08 Jan 2021 03:40:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-07T22:40:39', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'af8ca074-171f-4a6b-8257-52b7f2c3ed70' User entered '07 Jan 2021 22:40:39'	System	08 Jan 2021 03:40:42
	System	08 Jan 2021 03:40:42

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-13T22:09:55', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e39cb807-66b9-4143-a789-460d09154c76'	System	14 Jan 2021 03:10:09
User entered 'No (N)'	System	14 Jan 2021 03:10:09

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-13T22:09:58', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e39cb807-66b9-4143-a789-460d09154c76'	System	14 Jan 2021 03:10:09
User entered 'No (N)'	System	14 Jan 2021 03:10:09

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-13T22:10:03', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e39cb807-66b9-4143-a789-460d09154c76'	System	14 Jan 2021 03:10:09
User entered '13 Jan 2021 22:10:03'	System	14 Jan 2021 03:10:09

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-20T19:36:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2d9b1491-2199-4ce9-bc3c-5cfe28f19f74'	System	21 Jan 2021 00:36:27
User entered 'No (N)'	System	21 Jan 2021 00:36:27

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-20T19:36:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2d9b1491-2199-4ce9-bc3c-5cfe28f19f74'	System	21 Jan 2021 00:36:27
User entered 'No (N)'	System	21 Jan 2021 00:36:27

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-20T19:36:25', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '2d9b1491-2199-4ce9-bc3c-5cfe28f19f74'	System	21 Jan 2021 00:36:27
User entered '20 Jan 2021 19:36:25'	System	21 Jan 2021 00:36:27

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-28T16:28:54', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9282d315-54e2-4054-94af-234f344582af' User entered 'No (N)'	System	28 Jan 2021 21:29:07

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-28T16:28:57', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9282d315-54e2-4054-94af-234f344582af' User entered 'No (N)'	System	28 Jan 2021 21:29:07

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-01-28T16:29:01', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '9282d315-54e2-4054-94af-234f344582af' User entered '28 Jan 2021 16:29:01'	System	28 Jan 2021 21:29:07
	System	28 Jan 2021 21:29:07

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-05T20:13:09', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'beaf90ab-3225-4cf1-9f4a-ed9c433f5c80' User entered 'No (N)'	System	06 Feb 2021 01:13:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-05T20:13:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'beaf90ab-3225-4cf1-9f4a-ed9c433f5c80' User entered 'No (N)'	System	06 Feb 2021 01:13:22
	System	06 Feb 2021 01:13:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-05T20:13:19', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'beaf90ab-3225-4cf1-9f4a-ed9c433f5c80'	System	06 Feb 2021 01:13:22
User entered '05 Feb 2021 20:13:19'	System	06 Feb 2021 01:13:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:08', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa' User entered 'Yes (Y)'	System	14 Feb 2021 14:56:51
	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:13', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa' User entered 'No (N)'	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:18', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa' User entered 'No (N)'	System	14 Feb 2021 14:56:51
	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:30', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa' User entered 'Yes (Y)'	System	14 Feb 2021 14:56:51
	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:38', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa'	System	14 Feb 2021 14:56:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-14T09:56:44', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a46035a6-e0b6-491e-a571-c557ef465efa' User entered '14 Feb 2021 09:56:44'	System	14 Feb 2021 14:56:51
	System	14 Feb 2021 14:56:51

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-18T07:48:11', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5c18ce68-2ab5-4bf7-85c7-13cac9d6b629'	System	18 Feb 2021 12:48:25
User entered 'No (N)'	System	18 Feb 2021 12:48:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-18T07:48:15', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5c18ce68-2ab5-4bf7-85c7-13cac9d6b629'	System	18 Feb 2021 12:48:25
User entered 'No (N)'	System	18 Feb 2021 12:48:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-18T07:48:22', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '5c18ce68-2ab5-4bf7-85c7-13cac9d6b629' User entered '18 Feb 2021 07:48:22'	System	18 Feb 2021 12:48:25
	System	18 Feb 2021 12:48:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-25T21:55:28-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '95a3cc10-07bd-482d-a442-2349ca69b528'	System	26 Feb 2021 05:45:25
User entered 'No (N)'	System	26 Feb 2021 05:45:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-25T21:55:36-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '95a3cc10-07bd-482d-a442-2349ca69b528'	System	26 Feb 2021 05:45:25
User entered 'No (N)'	System	26 Feb 2021 05:45:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-25T21:55:40-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '95a3cc10-07bd-482d-a442-2349ca69b528' User entered '26 Feb 2021 02:55:40'	System	26 Feb 2021 05:45:25
	System	26 Feb 2021 05:45:25

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-06T08:37:35-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a702d106-69b7-42cd-9b5f-be80aadb248'	System	06 Mar 2021 13:37:45
User entered 'No (N)'	System	06 Mar 2021 13:37:45

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-06T08:37:39-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a702d106-69b7-42cd-9b5f-be80aadb248'	System	06 Mar 2021 13:37:45
User entered 'No (N)'	System	06 Mar 2021 13:37:45

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-06T08:37:43-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a702d106-69b7-42cd-9b5f-be80aadb248'	System	06 Mar 2021 13:37:45
User entered '06 Mar 2021 08:37:43'	System	06 Mar 2021 13:37:45

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-11T08:24:27-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b30e158-088c-48d0-91b4-2bd56b331b07'	System	11 Mar 2021 13:24:39
User entered 'No (N)'	System	11 Mar 2021 13:24:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-11T08:24:31-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b30e158-088c-48d0-91b4-2bd56b331b07'	System	11 Mar 2021 13:24:39
User entered 'No (N)'	System	11 Mar 2021 13:24:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-11T08:24:35-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '3b30e158-088c-48d0-91b4-2bd56b331b07'	System	11 Mar 2021 13:24:39
User entered '11 Mar 2021 08:24:35'	System	11 Mar 2021 13:24:39

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:00:19-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered 'Yes (Y)'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:00:23-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered 'No (N)'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:00:26-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered 'No (N)'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:00:35-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered 'Yes (Y)'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:00:40-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-20T22:01:10-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1688f000-8d3e-40bf-9db8-3fe34227033b'	System	21 Mar 2021 02:03:02
User entered '20 Mar 2021 22:01:10'	System	21 Mar 2021 02:03:02

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-28T22:28:03-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f6d26629-dadd-461b-80ea-ef129680877f'	System	29 Mar 2021 02:28:22
User entered 'No (N)'	System	29 Mar 2021 02:28:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-28T22:28:06-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f6d26629-dadd-461b-80ea-ef129680877f' User entered 'No (N)'	System	29 Mar 2021 02:28:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-03-28T22:28:18-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'f6d26629-dadd-461b-80ea-ef129680877f' User entered '28 Mar 2021 22:28:18'	System	29 Mar 2021 02:28:22
	System	29 Mar 2021 02:28:22

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-01T20:44:34-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '05fac72b-81f2-4ad7-946e-87f03c1a384d' User entered 'No (N)'	System	02 Apr 2021 00:44:52

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-01T20:44:37-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '05fac72b-81f2-4ad7-946e-87f03c1a384d' User entered 'No (N)'	System	02 Apr 2021 00:44:52

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-01T20:44:41-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '05fac72b-81f2-4ad7-946e-87f03c1a384d'	System	02 Apr 2021 00:44:52
User entered '01 Apr 2021 20:44:41'	System	02 Apr 2021 00:44:52

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-07T20:54:08-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1b5a5f84-5fbc-4ae1-a6d9-6c51c6b6aaef' User entered 'No (N)'	System	08 Apr 2021 00:54:26
	System	08 Apr 2021 00:54:26

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-07T20:54:15-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1b5a5f84-5fbc-4ae1-a6d9-6c51c6b6aaef'	System	08 Apr 2021 00:54:26
User entered 'No (N)'	System	08 Apr 2021 00:54:26

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-07T20:54:20-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '1b5a5f84-5fbc-4ae1-a6d9-6c51c6b6aaef'	System	08 Apr 2021 00:54:26
User entered '07 Apr 2021 20:54:20'	System	08 Apr 2021 00:54:26

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-15T19:49:36-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e1492c55-7e76-400a-b05e-68e565c53ad7'	System	15 Apr 2021 23:49:57
User entered 'Yes (Y)'	System	15 Apr 2021 23:49:57

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-15T19:49:40-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e1492c55-7e76-400a-b05e-68e565c53ad7' User entered 'No (N)'	System	15 Apr 2021 23:49:57

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-15T19:49:43-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e1492c55-7e76-400a-b05e-68e565c53ad7' User entered 'No (N)'	System	15 Apr 2021 23:49:57
	System	15 Apr 2021 23:49:57

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-15T19:49:49-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e1492c55-7e76-400a-b05e-68e565c53ad7'	System	15 Apr 2021 23:49:57
User entered 'No (N)'	System	15 Apr 2021 23:49:57

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-15T19:49:54-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'e1492c55-7e76-400a-b05e-68e565c53ad7' User entered '15 Apr 2021 19:49:54'	System	15 Apr 2021 23:49:57
	System	15 Apr 2021 23:49:57

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:29-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered 'Yes (Y)'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:32-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered 'Yes (Y)'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:35-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:39-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered 'No (N)'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:47-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered 'No (N)'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-22T20:24:51-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'c287c087-0efb-4b4e-8fde-d0c8a8e6a218'	System	23 Apr 2021 00:25:01
User entered '22 Apr 2021 20:24:51'	System	23 Apr 2021 00:25:01

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-30T16:33:05-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a0d7273f-62e8-48d0-9ba6-82e0d2b4312d' User entered 'No (N)'	System	30 Apr 2021 20:33:15
	System	30 Apr 2021 20:33:15

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

Have you been exposed to someone with 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 (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-30T16:33:08-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a0d7273f-62e8-48d0-9ba6-82e0d2b4312d' User entered 'No (N)'	System	30 Apr 2021 20:33:15
	System	30 Apr 2021 20:33:15

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-04-30T16:33:12-04:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: 'a0d7273f-62e8-48d0-9ba6-82e0d2b4312d' User entered '30 Apr 2021 16:33:12'	System	30 Apr 2021 20:33:15
	System	30 Apr 2021 20:33:15

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 08:56:49

US3202217

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:43:30

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 08:56:49
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 08:56:49

US3202217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:30

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-27T11:39:28-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0b0f71ed-6b94-4502-92d0-8c17c77a55be'	System	27 Feb 2021 16:39:37
User entered 'No (N)'	System	27 Feb 2021 16:39:37

US3202217

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:43:30

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 05:38:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (A90DD49B-227B-4665-B350-BB100AB23D80)', Time: '2021-02-27T11:39:34-05:00', User OID: 'PatientReportedOutcome (US3202217)', ODM File OID: '0b0f71ed-6b94-4502-92d0-8c17c77a55be' User entered '27 Feb 2021 16:39:34'	System	27 Feb 2021 16:39:37
	System	27 Feb 2021 16:39:37

US3202217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:44:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:46:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:31:32

US3202217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:44:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:46:20
User entered '10 Nov 2020'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:31:32

US3202217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:44:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:46:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	10 Nov 2020 19:37:30
reason for change: Data Entry Error	(b) (4), (b) (6)	
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 19:31:43
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Nov 2020 19:31:32

US3202217

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:44:50
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:46:20
User entered 'LVM SUB CALLED BACK' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:37:30
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).		10 Nov 2020 19:31:53
User entered 'LVM' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Nov 2020 19:31:53
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	10 Nov 2020 19:31:43
User entered empty.	(b) (4), (b) (6)	10 Nov 2020 19:31:32

US3202217

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:44:56
User signature succeeded.	Mark McKenzie (b) (4)	26 Mar 2021 12:46:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:31:59

US3202217

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:26:25
User entered 'I'	System	10 Nov 2020 19:31:59

US3202217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 21:53:02

US3202217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:07
User entered '11 Dec 2020'	(b) (4), (b) (6)	11 Dec 2020 21:53:02

US3202217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Dec 2020 21:53:02

US3202217

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:07
User entered empty.	(b) (4), (b) (6)	11 Dec 2020 21:53:02

US3202217

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Dec 2020 21:53:05

US3202217

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User entered 'I'	System	11 Dec 2020 21:53:05

US3202217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:30
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:24:43

US3202217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:30
User entered '14 Jan 2021'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:24:43

US3202217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:30
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:24:43

US3202217

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:30
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:24:43

US3202217

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:45:46
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:24:50

US3202217

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User entered 'I'	System	14 Jan 2021 16:24:50

US3202217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:47:09
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:36:54

US3202217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:47:09
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	22 Feb 2021 12:05:57
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'pd noted oow' (Site from System).	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:36:59
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	21 Feb 2021 17:36:54
User entered '21 Feb 2021'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:36:54

US3202217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:47:09
User entered 'Contact Made (CONTACT MADE)'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:36:54

US3202217

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:47:09
User entered empty.	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:36:54

US3202217

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:47:15
User entered 'Yes (Y)'	zackery harmon (b) (4) (b) (4)	21 Feb 2021 17:37:04

US3202217

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:24:29
User entered 'I'	System	21 Feb 2021 17:37:04

US3202217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:12

US3202217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered '19 Mar 2021'	(b) (4)	
	Teresa Deese (b) (4)	19 Mar 2021 16:41:12

US3202217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[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 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:19:43
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:12

US3202217

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered 'VISIT4'	System	19 Mar 2021 16:41:12

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered empty.	System	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered empty.	System	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered empty.	System	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered empty.	System	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:20
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered empty.	System	29 Mar 2021 12:58:07

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49

US3202217

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49

US3202217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:17

US3202217

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:34
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	19 Mar 2021 16:41:17

US3202217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:32

US3202217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered '19 Mar 2021'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:32

US3202217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:40
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered '12:08'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:32

US3202217

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered '19 Mar 2021 12:08'	System	19 Mar 2021 16:41:32

US3202217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:20:46
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
Signature has been broken.	(b) (4) Lilian Nukuna (b) (4)	14 Apr 2021 16:23:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Lilian Nukuna (b) (4)	14 Apr 2021 16:23:55
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	19 Mar 2021 16:41:23

US3202217

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 07:15:49
User entered '1'	System	14 Apr 2021 16:23:55
User entered empty.	System	19 Mar 2021 16:41:23

US3202217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 16:24:13

US3202217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
	(b) (4)	
User entered '14 Apr 2021'	Lilian Nukuna (b) (4)	14 Apr 2021 16:24:13

US3202217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4)	14 Apr 2021 16:24:13

US3202217

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
	(b) (4)	
User entered empty.	Lilian Nukuna (b) (4)	14 Apr 2021 16:24:13

US3202217

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	15 Apr 2021 19:20:39
	(b) (4)	
User entered 'Yes (Y)'	Lilian Nukuna (b) (4)	14 Apr 2021 16:24:18

US3202217

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Apr 2021 16:24:18

US3202217

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:33
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:38

US3202217

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:33
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 14:14:38

US3202217

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:33
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:38

US3202217

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

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 14:14:38

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:39
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
User entered '0'	(b) (4) Teresa Deese (b) (4)	22 Apr 2021 16:52:31
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:52:20

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:39
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 18:49:50
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
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).	Teresa Deese (b) (4)	22 Apr 2021 16:53:05
User entered 'Amendment 6 or later (Amendment 6 or later)'	Teresa Deese (b) (4)	22 Apr 2021 16:52:31
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 08:50:50
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:52:20

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered 'Placebo (Placebo)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:41
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '1'	System	25 Jan 2021 14:14:52

US3202217

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

Form: Unblinding

Generated On: 09 Jun 2021 15:43:30

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	25 Jan 2021 14:14:52

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	25 Jan 2021 14:15:38
DataPoint set to visible.	System	25 Jan 2021 14:14:52

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	25 Jan 2021 14:15:38
DataPoint set to visible.	System	25 Jan 2021 14:14:52

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '08:30'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '25 Jan 2021 08:30'	System	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '37' C	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '64'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'bpm'	System	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '16'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'breaths/min'	System	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '150'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '86'	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 14:15:38

US3202217

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:43:30

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	25 Jan 2021 14:15:38
DataPoint set to visible.	System	25 Jan 2021 14:14:52

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '09:37'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '25 Jan 2021 09:37'	System	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '36.8' C	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '61'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'bpm'	System	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '16'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'breaths/min'	System	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '147'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:49:30
User entered '86'	Teresa Deese (b) (4)	25 Jan 2021 15:03:25

US3202217

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	25 Jan 2021 15:03:25

US3202217

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:39
User entered 'No (N)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:30

US3202217

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:39
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 15:03:30

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered empty.	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mRNA-1273'	System	25 Jan 2021 15:03:48
DataPoint set to visible.	System	25 Jan 2021 14:14:52

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered '08:48'	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '25 Jan 2021 08:48'	System	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 15:52:56
User entered 'ONCE'	System	25 Jan 2021 15:03:48

US3202217

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

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 15:03:48

US3202217

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:03
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 15:04:01

US3202217

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:03
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 15:04:01

US3202217

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:03
User entered '08:46'	Teresa Deese (b) (4)	25 Jan 2021 15:04:01

US3202217

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '25 Jan 2021 08:46'	System	25 Jan 2021 15:04:01

US3202217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:10
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 15:04:13

US3202217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:10
User entered '25 Jan 2021'	Teresa Deese (b) (4)	25 Jan 2021 15:04:13

US3202217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:30

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:10
User entered '08:44'	Teresa Deese (b) (4)	25 Jan 2021 15:04:13

US3202217

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:43:30

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '25 Jan 2021 08:44'	System	25 Jan 2021 15:04:13

US3202217

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

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:53:19
User entered 'Yes (Y)'	Teresa Deese (b) (4)	25 Jan 2021 15:04:20

US3202217

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

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	25 Jan 2021 15:04:20

US3202217

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:56
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	04 Feb 2021 22:24:43

US3202217

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:56
User entered '4 Feb 2021'	Lilian Nukuna (b) (4) (b) (4)	04 Feb 2021 22:24:43

US3202217

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:56
User entered 'Contact Made (CONTACT MADE)'	Lilian Nukuna (b) (4) (b) (4)	04 Feb 2021 22:24:43

US3202217

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:54:56
User entered empty.	Lilian Nukuna (b) (4) (b) (4)	04 Feb 2021 22:24:43

US3202217

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:55:05
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	04 Feb 2021 22:24:49

US3202217

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	04 Feb 2021 22:24:49

US3202217

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	04 Feb 2021 22:24:49
DataPoint set to visible.	System	04 Feb 2021 22:24:49

US3202217

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:18
User entered 'Yes (Y)'	Teresa Deese (b) (4)	02 Mar 2021 14:16:53

US3202217

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:18
User entered '1 Mar 2021'	Teresa Deese (b) (4)	02 Mar 2021 14:16:53

US3202217

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:48:18
User entered 'Clinic (Clinic)'	Teresa Deese (b) (4)	02 Mar 2021 14:16:53

US3202217

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'OLD29'	System	02 Mar 2021 14:16:53

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User accepted default value 'Pre-Dose (PREDOSE)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered 'Yes (Y)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '1 Mar 2021'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '14:46' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '14:57'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '1 Mar 2021 14:46'	System	02 Mar 2021 14:19:24
User entered '1 Mar 2021 14:57'	System	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '36.8' C reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '37.2' C	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '90' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '77'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'bpm'	System	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Mar 2021 14:19:35
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	02 Mar 2021 14:19:35
User entered '16' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:35
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	02 Mar 2021 14:19:24
User entered '161' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '16'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'breaths/min'	System	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '147' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '152'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '85' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:19:24
User entered '93'	Teresa Deese (b) (4)	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	02 Mar 2021 14:18:12

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User accepted default value 'Post-Dose (POSTDOSE)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered 'Yes (Y)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '1 Mar 2021'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '15:35'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '1 Mar 2021 15:35'	System	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '37.2' C	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered 'Oral (Oral)'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '77'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'bpm'	System	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '16'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'breaths/min'	System	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '152'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 15:59:35
User entered '93'	Teresa Deese (b) (4)	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mmHg'	System	02 Mar 2021 14:18:40

US3202217

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:34
User entered 'No (N)'	Teresa Deese (b) (4)	02 Mar 2021 14:19:43

US3202217

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:34
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:19:43

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered 'Yes (Y)'	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'mRNA-1273'	System	02 Mar 2021 14:19:59
DataPoint set to visible.	System	04 Feb 2021 22:24:49

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered '1 Mar 2021'	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered '14:57'	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '1 Mar 2021 14:57'	System	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered 'Left Arm (LEFT ARM)'	Teresa Deese (b) (4)	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:00:55
User entered 'ONCE'	System	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:43:30

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'INTRAMUSCULAR'	System	02 Mar 2021 14:19:59

US3202217

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:01
User entered 'Yes (Y)'	Teresa Deese (b) (4)	02 Mar 2021 14:20:15

US3202217

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	02 Mar 2021 14:20:15

US3202217

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:36
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 20:32:25

US3202217

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:36
User entered '8 Mar 2021'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 20:32:25

US3202217

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 20:32:25

US3202217

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:43:30

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:36
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	08 Mar 2021 20:32:40
User entered 'left a voice message' reason for change: Data Entry Error	Lilian Nukuna (b) (4)	08 Mar 2021 20:32:40
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	08 Mar 2021 20:32:25
	Lilian Nukuna (b) (4)	08 Mar 2021 20:32:25
	(b) (4)	

US3202217

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:01:41
User entered 'Yes (Y)'	Lilian Nukuna (b) (4) (b) (4)	08 Mar 2021 20:32:49

US3202217

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:43:30

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'I'	System	08 Mar 2021 20:32:49

US3202217

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:06

US3202217

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User closed query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'noted' (Site from System).	(b) (4), (b) (6)	08 Apr 2021 08:19:01
Query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' answered with 'noted' (Site from System).	Teresa Deese (b) (4)	07 Apr 2021 14:14:11
User opened query 'OL-D57 Visit Date is < 25 days or > 42 days after OL-D29 visit vaccination. Please reconcile or confirm dates.' (Site from System).	System	07 Apr 2021 14:13:46
User entered '19 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	07 Apr 2021 14:13:46
User entered '6 Apr 2021'	Teresa Deese (b) (4)	06 Apr 2021 16:40:06

US3202217

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:50
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Clinic (Clinic)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:06

US3202217

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:43:30

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered 'OLD57'	System	06 Apr 2021 16:40:06

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:22:57
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered empty.	System	06 Apr 2021 16:40:28

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45

US3202217

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:43:30

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45

US3202217

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:23:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:33

US3202217

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:43:30

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:23:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered empty.	(b) (4)	
	Teresa Deese (b) (4)	06 Apr 2021 16:40:33

US3202217

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:23:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:45

US3202217

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:23:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	07 Apr 2021 14:14:01
User entered '19 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	07 Apr 2021 14:14:01
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).		
User entered '6 Apr 2021'	System	07 Apr 2021 14:13:46
	Teresa Deese (b) (4)	06 Apr 2021 16:40:45

US3202217

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:23:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered '12:08'	(b) (4) Teresa Deese (b) (4)	06 Apr 2021 16:40:45

US3202217

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:43:30

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:11:45
User entered '19 Mar 2021 12:08'	System	07 Apr 2021 14:14:01
User entered '6 Apr 2021 12:08'	System	06 Apr 2021 16:40:45

US3202217

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:43:30

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:06:32
User closed query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 12:33:15
Query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'that's b/c there is no new AE' (Site from DM).	Teresa Deese (b) (4)	29 Mar 2021 12:59:08
User opened query 'Per DM CLR: Per Day 215 on Safety Follow-up Diary, Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:26:06
User signature succeeded.	Mark McKenzie (b) (4)	19 Mar 2021 13:10:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Teresa Deese (b) (4)	02 Mar 2021 14:30:57
User entered 'No (N)'	zackery harmon (b) (4)	03 Oct 2020 15:54:00

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 13:36:46
User entered	System	19 Apr 2021 13:36:35
'USA-US128-2021-mRNA-1273-P301000020'		
User entered 'New'	(b) (4), (b) (6)	19 Apr 2021 13:36:35

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:32:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:32:46
Data point term sent to Coder	System	16 Apr 2021 17:23:22
Coding entries removed.	Erica Osmundsen (b) (4)	16 Apr 2021 17:23:19
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 17:23:19
User entered 'WORSENING RIGHT KNEE OSTEOARTHRITIS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:23:19
User signature succeeded.	Mark McKenzie (b) (4) (b) (4)	15 Mar 2021 12:15:02
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Knee pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 14:33:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Mar 2021 14:33:43
Data point term sent to Coder	System	02 Mar 2021 14:32:59
User entered 'worsening right knee pain'	Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'Yes (Y)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered '11 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '01 Nov 2020'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered '12 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '11 Feb 2021'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'No (N)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered '1' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered '11 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '12 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 14:02:36
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered '12 Apr 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

US3202217

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'Not Related (NOT RELATED)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:01:50
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 17:19:07
	(b) (4), (b) (6)	
User closed query 'PV Query: As first dose of mRNA -1273 was administered prior to event and second dose was administered after event onset, please consider updating action taken from N/A to No Change.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 20:11:16
User closed query 'per CCG response should be -"none" please verify' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 16:27:20
Query 'per CCG response should be -"none" please verify' answered with 'UPDATED' (Site from CRA).	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:49
	(b) (4)	
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:36
	(b) (4)	
User entered 'None (NONE)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:36
	(b) (4)	
User opened query 'per CCG response should be -"none" please verify' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 14:44:00
DataPoint Un-verified.	(b) (4), (b) (6)	23 Apr 2021 14:43:31
	(b) (4)	
Query 'PV Query: As first dose of mRNA -1273 was administered prior to event and second dose was administered after event onset, please consider updating action taken from N/A to No Change.' answered with 'no change' is not an option' (Site from Safety).	Teresa Deese (b) (4)	23 Apr 2021 13:15:30
	(b) (4)	
User opened query 'PV Query: As first dose of mRNA -1273 was administered prior to event and second dose was administered after event onset, please consider updating action taken from N/A to No Change.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:39:24
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
	(b) (4)	
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Teresa Deese (b) (4)	02 Mar 2021 14:32:30
	(b) (4)	

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered '0'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User closed query 'Per DM CLR: Please review response as there is a Concomitant Medication (#12) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 08:28:52
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
Query 'Per DM CLR: Please review response as there is a Concomitant Medication (#12) recorded that matches this AE during this timeframe. Please review and update this field. ' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	12 Mar 2021 18:43:05
User entered '1' reason for change: Data Entry Error	Teresa Deese (b) (4)	12 Mar 2021 18:42:59
User opened query 'Per DM CLR: Please review response as there is a Concomitant Medication (#12) recorded that matches this AE during this timeframe. Please review and update this field. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 06:04:21
User entered '0'	Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'I'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 14:39:55
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered empty.	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 18:08:09
User closed query 'PV Query: Please confirm if elevated blood pressure was significant and considered a separate event. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:21:56
User closed query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 15:19:59
Query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so. ' answered with 'done' (Site from Safety).	Erica Osmundsen (b) (4)	30 Apr 2021 16:07:03
DataPoint Un-verified.	Erica Osmundsen (b) (4)	30 Apr 2021 16:06:14
Signature has been broken.	Erica Osmundsen (b) (4)	30 Apr 2021 16:06:14
User entered 'HAD OUTPATIENT SURGERY PER SUBJECT BUT UPON RECEIPT OF RECORDS, IT WAS LEARNED THAT THE SUBJECT STAYED OVERNIGHT AT HOSPITAL FOR POST-OP OBSERVATION, THUS MAKING THIS PLANNED SURGERY AN SAE PER THIS PROTOCOL'S GUIDELINES. NO SIGNIFICANT ABNORMALITIES ON LABS OR PATHOLOGY. RECORDS WERE REDACTED AND SCANNED TO SAFETY TEAM WHICH INCLUDED LABS--Summary of 12/FEB/2021 labs that were outside normal range (ref range in parentheses): Glucose 137 (60-99) mg/dL; WBC 12.9 (4.5-10.5) K/uL; RBC 4.18 (4.7-6.1) M/uL; H/H 13.0/38.3 (13.6-17.8) g/dL/ 40-51) %; neut 11.18 (2.02-8.4) K/uL Lymph 0.61 (.67-4.3) K/uL' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	30 Apr 2021 16:06:14

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:43:30

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm if elevated blood pressure was significant and considered a separate event. ' answered with 'PI CONFIRMED THAT BRIEF ELEVATION IN BLOOD PRESSURE ON DATE OF SURGERY IS NOT A SEPARATE EVENT TO BE REPORTED AS AE. COMMON OCCURRENCE WITH PAIN AND ANXIETY RELATED TO SURGERY. MEDICATION CHANGE NOT NEEDED AND BLOOD PRESSURE BACK TO BASELINE AT DISCHARGED.' (Site from Safety).	Erica Osmundsen (b) (4)	30 Apr 2021 15:36:23
User opened query 'PV Query: Please provide units and normal reference ranges for labs. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:34:17
User opened query 'PV Query: Please confirm if elevated blood pressure was significant and considered a separate event. ' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 20:34:09
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:01:50
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 20:11:39
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)	23 Apr 2021 20:11:34
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)	23 Apr 2021 20:11:29
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 16:28:01

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'RECORDS RECEIVED AND D/C SUMMARY REDACTED AND SENT TO SAFETY' (Site from Safety).	Erica Osmundsen (b) (4)	23 Apr 2021 15:33:27
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 'UPDATED NARRATIVE AND SENT RECORDS TO SAFETY PER REQUEST' (Site from Safety).	Erica Osmundsen (b) (4)	23 Apr 2021 15:33:09
DataPoint Un-verified.	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:36
Signature has been broken.	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:36
User entered 'HAD OUTPATIENT SURGERY PER SUBJECT BUT UPON RECEIPT OF RECORDS, IT WAS LEARNED THAT THE SUBJECT STAYED OVERNIGHT AT HOSPITAL FOR POST-OP OBSERVATION, THUS MAKING THIS PLANNED SURGERY AN SAE PER THIS PROTOCOL'S GUIDELINES. NO SIGNIFICANT ABNORMALITIES ON LABS OR PATHOLOGY' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	23 Apr 2021 15:32:36
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 'not done' (Site from Safety).	Teresa Deese (b) (4)	23 Apr 2021 13:16:48

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 12:39:08
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)	23 Apr 2021 12:38:57
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)	23 Apr 2021 12:38:48
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User entered 'HAD OUTPATIENT SURGERY per subject but upon receipt of records, it was learned that the subject stayed overnight at hospital for post-op observation, thus making this planned surgery an SAE per this protocol's guidelines.' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 13:54:11
User signature succeeded.	Mark McKenzie (b) (4)	15 Mar 2021 12:15:02
User entered 'had outpatient surgery-'	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:32:30

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 13:54:11
User entered '0'	System	02 Mar 2021 14:32:30

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Mar 2021 14:32:30

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Apr 2021 13:54:11

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Non-site specific procedural complications, PT: Procedural pain, LLT: Postoperative pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:39:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Apr 2021 07:39:31
Data point term sent to Coder	System	16 Apr 2021 17:27:25
User entered 'ACUTE POST-OPERATIVE PAIN'	Erica Osmundsen (b) (4) (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

Form: Adverse Events (2)

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Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User entered empty.	System	16 Apr 2021 17:26:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '26 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User entered empty.	System	16 Apr 2021 17:26:54

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

Form: Adverse Events (2)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Not Related (NOT RELATED)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Not Applicable (NOT APPLICABLE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'l'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:39:55
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User entered '0'	System	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55
User entered '1'	System	16 Apr 2021 17:26:54

US3202217

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:43:30

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:22:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:43:30

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:25
Query 'Source also = 1 gram Tranexamic Acid 11Feb IV also. Did subject resume Eliquis after Warfarin was d/c'd? Please verify' canceled (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 18:46:40
User opened query 'Source also = 1 gram Tranexamic Acid 11Feb IV also. Did subject resume Eliquis after Warfarin was d/c'd? Please verify' (Site from CRA).	(b) (4), (b) (6)	19 Apr 2021 17:05:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:08:32
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)'	(b) (4) Erica Osmundsen (b) (4)	20 Oct 2020 21:42:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:44:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:44:34
Data point term sent to Coder User entered 'ROSUVASTATIN'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23 20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'HYPERLIPIDEMIA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '20'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2010'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:43:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
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)	20 Oct 2020 21:45:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:45:20
Data point term sent to Coder	System	20 Oct 2020 21:44:27
User entered 'TRAZODONE'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '100'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:44:14

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:26:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:26:36
Data point term sent to Coder	System	20 Oct 2020 21:45:29
User entered 'CARVEDILOL'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'CARDIAC ARRHYTHMIA'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '25'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2018'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:44:45

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:12:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Dec 2020 21:12:43
Data point term sent to Coder	System	09 Dec 2020 21:11:41
Coding entries removed.	Erica Osmundsen (b) (4)	09 Dec 2020 21:11:09
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 21:47:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Oct 2020 21:47:24
Data point term sent to Coder	System	20 Oct 2020 21:46:30
User entered 'ELIQUIS'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:21:40
DataPoint Un-verified.	Erica Osmundsen (b) (4)	09 Dec 2020 21:11:09
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Dec 2020 21:11:09
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 17:21:47
User closed query 'please verify indication as anticoagulant is indicated on source' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 17:21:43
Query 'please verify indication as anticoagulant is indicated on source' answered with 'UPDATED PER SOURCE' (Site from CRA).	Erica Osmundsen (b) (4)	09 Dec 2020 21:11:22
User entered 'CARDIAC ARRHYTHMIA' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Dec 2020 21:11:09
User opened query 'please verify indication as anticoagulant is indicated on source' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:47:03
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 20:46:19
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'CARDIOVASCULAR PROPHYLAXIS'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '5'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2018'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:17:43
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:17:44
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
User entered '11 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:29:15
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User entered '2'	System	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User entered '1'	System	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:04
User entered '804 (804)'	System	20 Oct 2020 21:45:46

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:47:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:47:24
Data point term sent to Coder User entered 'LOSARTAN'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:46:30 20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '100'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:46:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:48:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:48:26
Data point term sent to Coder User entered 'SPIRONOLACTONE'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:47:31 20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '25'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:46:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:48:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:48:26
Data point term sent to Coder User entered 'AMLODIPINE'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:47:32 20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '10'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:47:22

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIGOUT PREPARATIONS, ATC: ANTIGOUT PREPARATIONS, ATC: PREPARATIONS INHIBITING URIC ACID PRODUCTION, PRODUCT: ALLOPURINOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:49:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:49:28
Data point term sent to Coder User entered 'ALLOPURINOL'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:48:33 20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'GOUT'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '300'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2005'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:47:47

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
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)	21 Oct 2020 05:41:24
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 05:41:24
Data point term sent to Coder	System	20 Oct 2020 21:48:34
User entered 'GABAPENTIN'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'CHRONIC NEUROPATHIC PAIN'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '900'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN Jun 2020'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:48:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: PERCOCET [OXYCODONE HYDROCHLORIDE;PARACETAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:55:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 04:55:27
Data point term sent to Coder	System	20 Oct 2020 21:51:41
User entered 'PERCOCET 7.5/325 MG'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'CHRONIC NEUROPATHIC PAIN'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'I'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'tablet (TABLET)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2017'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:18:56
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
User entered 'No (N)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:18:58
DataPoint Un-verified.	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
User entered '12 Feb 2021' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:34:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User entered empty.	System	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User entered empty.	System	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:13
User entered empty.	System	20 Oct 2020 21:50:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:52:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Oct 2020 21:52:24
Data point term sent to Coder User entered 'OMEPRAZOLE'	System Erica Osmundsen (b) (4)	20 Oct 2020 21:51:40 20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'BARRETT'S ESOPHAGUS'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '40'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN UNK 2012'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:59:29
DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 16:56:51
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Oct 2020 21:51:28

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:16:17
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 13:00:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 13:00:07
User closed query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:18:30
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC PAIN RIGHT KNEE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:18:02
Data point term sent to Coder	System	25 Jan 2021 15:07:51
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC PAIN RIGHT KNEE; update Con Med indication or provide clarification. ' answered with 'no worsening' (Site from DM).	Teresa Deese (b) (4)	25 Jan 2021 15:07:31
Query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' answered with 'done' (Site from DM).	Teresa Deese (b) (4)	25 Jan 2021 15:07:21

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Teresa Deese (b) (4)	25 Jan 2021 15:07:05
Coding entries removed.	Teresa Deese (b) (4)	25 Jan 2021 15:07:05
User entered 'VOLTARAN GEL- 1% diclofenac sodium' reason for change: Data Entry Error	Teresa Deese (b) (4)	25 Jan 2021 15:07:05
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening CHRONIC PAIN RIGHT KNEE; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:00:53
User opened query 'Per DM CLR: Please provide the strength of this topical medication in the medication name, and consider recording the number of applications instead (e.g. dose=1; unit=application). Review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 11:59:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:41:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:41:48
Data point term sent to Coder	System	09 Dec 2020 21:09:40
Coding entries removed.	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:42
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:55:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 05:55:38
Data point term sent to Coder	System	11 Nov 2020 19:03:44
User entered 'VOLTARAN GEL'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User closed query 'Please document the date of surgery in the source' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 17:22:53
	(b) (4), (b) (6)	10 Dec 2020 17:22:49
Query 'Please document the date of surgery in the source' answered with	Erica Osmundsen (b) (4)	09 Dec 2020 21:10:29
'DOCUMENTED--SURGERY OCCURRED IN APRIL 2020 BUT PAIN HAS CONTINUED, UPDATED MEDICAL HISTORY PER SOURCE DOCUMENTATION OF PATIENT REPORT' (Site from CRA).		
User entered 'CHRONIC PAIN RIGHT KNEE' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Dec 2020 21:09:26
User entered 'CHRONIC RIGHT KNEE PAIN' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	09 Dec 2020 21:08:42
User opened query 'Please document the date of surgery in the source' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:45:46
DataPoint Un-verified.	(b) (4), (b) (6)	09 Dec 2020 20:45:27
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'PAIN FROM KNEE SURGERY'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:03:53
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered '4' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	25 Jan 2021 15:05:46
User closed query 'Per DM CLR: Please note, 4 g pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 09:06:53
Query 'Per DM CLR: Please note, 4 g pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' answered with 'correction made' (Site from DM).	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:27:54
DataPoint Un-verified.	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:26:53
User entered '1' reason for change: Data Entry Error	Lilian Nukuna (b) (4) (b) (4)	14 Jan 2021 16:26:53
User opened query 'Per DM CLR: Please note, 4 g pertains to drug concentration/strength. So please verify if the DOSE reflecting the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = application) would be more appropriate recording. If so, update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 09:29:11
DataPoint Verified.	(b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '4'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'g (g)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'twice daily (BID)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'UN Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 15:42:27
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Nov 2020 19:03:25

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 09:41:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 09:41:42
Data point term sent to Coder	System	07 Apr 2021 14:15:39
Coding entries removed.	Teresa Deese (b) (4)	07 Apr 2021 14:14:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:16:50
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:53:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 08:53:28
Data point term sent to Coder	System	29 Mar 2021 13:02:34
User entered 'PREDNISOLONE' reason for change:	Teresa Deese (b) (4)	29 Mar 2021 13:01:40
Data Entry Error		
Data point term sent to Coder	System	29 Mar 2021 13:01:32
Coding entries removed.	Teresa Deese (b) (4)	29 Mar 2021 13:00:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:02:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 12:02:36
Data point term sent to Coder	System	19 Mar 2021 16:41:14
User entered 'prednisolone (14 days)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:16:52
User entered 'No (N)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:19:37
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User closed query 'Please verify as source note = ongoing back pain but AE log = Chronic knee pain' (Site from CRA).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 15:48:36
Query 'Please verify as source note = ongoing back pain but AE log = Chronic knee pain' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	07 Apr 2021 14:15:12
User entered 'CHRONIC back PAIN' reason for change: Data Entry Error	Teresa Deese (b) (4)	07 Apr 2021 14:14:48
User opened query 'Please verify as source note = ongoing back pain but AE log = Chronic knee pain' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:18:45
User closed query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 13:02:17
Query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' answered with 'cond corrected' (Site from DM).	Teresa Deese (b) (4)	29 Mar 2021 13:01:02
User entered 'CHRONIC knee PAIN' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 13:00:54
User opened query 'Per DM CLR: Please note there is no ongoing MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 02:46:55
User entered 'chronic back pain'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:23
User entered '10'	Teresa Deese (b) (4) [REDACTED] [REDACTED]	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:24
User entered 'mg (mg)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:27
User entered empty.	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:28
User entered 'once daily (QD)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:30
User entered empty.	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:32
User entered 'Oral (ORAL)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:36
User entered empty.	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:39
User entered '18 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 13:02:06
User entered '19 Mar 2021'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:47
User entered '0'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:50
User entered 'No (N)' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 13:01:32
User entered 'Yes (Y)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:52
User entered '28 Mar 2021' reason for change: Data Entry Error	Teresa Deese (b) (4)	29 Mar 2021 13:01:32
User entered empty.	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:17:55
User entered 'No (N)'	Teresa Deese (b) (4)	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Mar 2021 16:40:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:19:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: DRUGS USED IN ADDICTIVE DISORDERS, ATC: DRUGS USED IN NICOTINE DEPENDENCE, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:16:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 08:16:32
Data point term sent to Coder	System	16 Apr 2021 17:39:37
User entered 'BUPROPION'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:19:55
User entered 'No (N)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:19:57
User entered 'CHRONIC NEUROPATHIC PAIN IN LEFT LEG AND LEFT HAND'	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:00
User entered '300'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:02
User entered 'mg (mg)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:04
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:06
User entered 'once daily (QD)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:08
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:10
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:11
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:13
User entered '30 Jan 2021'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:15
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:16
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:18
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:20
User entered 'No (N)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 17:39:08

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:50:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:50:00
Data point term sent to Coder	System	16 Apr 2021 17:48:51
User entered 'HYDRALAZINE'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:29
User entered 'No (N)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:30
User entered 'HYPERTENSION'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:33
User entered '10'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:35
User entered 'mg (mg)'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:36
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:39
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:41
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:43
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:44
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:46
User entered '04 Jan 2021'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:48
User entered '0'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:50
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:53
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:20:55
User entered 'No (N)'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 17:48:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:07
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DEXMETHASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:38:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:38:36
Data point term sent to Coder	System	16 Apr 2021 17:51:53
User entered 'DEXMETHASONE'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:12
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:14
User entered 'WORSENING RIGHT KNEE OSTEOARTHRITIS'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:17
User entered '8'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:18
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:20
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:22
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:24
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:26
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:39
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:40
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:52
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:54
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:55
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:21:57
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User entered empty.	System	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User entered empty.	System	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:37
User entered empty.	System	16 Apr 2021 17:50:53

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:50
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:43:34
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 Apr 2021 13:43:34
Data point term sent to Coder	System	16 Apr 2021 17:51:52
User entered 'DOCUSATE SODIUM'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:51
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:53
User entered 'PREVENTION OF OPIOID-INDUCED CONSTIPATION POST-SURGERY'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:55
User entered '100'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:56
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:50:58
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:01
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:03
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:04
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:06
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:08
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:10
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:11
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:14
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:15
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User entered empty.	System	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User entered empty.	System	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:42
User entered empty.	System	16 Apr 2021 17:51:51

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: H2-RECEPTOR ANTAGONISTS, PRODUCT: FAMOTIDINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:54:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:54:54
Data point term sent to Coder	System	16 Apr 2021 17:53:55
Data point term sent to Coder	System	16 Apr 2021 17:52:54
User entered 'FAMOTIDINE'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:35
User entered 'BARRETT'S ESOPHAGUS' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 17:53:22
User entered 'GASTROESOPHAGEAL REFLUX DISEASE'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:38
User entered '10'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:39
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:41
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:42
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:44
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:46
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:48
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:50
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:51
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:53
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:55
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:51:57
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User entered empty.	System	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User entered empty.	System	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:49
User entered empty.	System	16 Apr 2021 17:52:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:55:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:55:56
Data point term sent to Coder	System	16 Apr 2021 17:54:56
User entered 'DIPHENHYDRAMINE'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:04
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:05
User entered 'INSOMNIA'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:07
User entered '12.5'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:09
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:11
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:12
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:14
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:15
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:19
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:21
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:24
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:26
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:28
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:30
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User entered empty.	System	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User entered empty.	System	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:15:53
User entered empty.	System	16 Apr 2021 17:54:06

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:57:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 13:57:31
Data point term sent to Coder	System	16 Apr 2021 17:54:56
User entered 'HYDROCODONE / ACETAMINOPHEN'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:36
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:38
User entered 'WORSENING OF RIGHT KNEE OSTEOARTHRITIS'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:40
User entered 'I'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:42
User entered 'tablet (TABLET)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:44
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:45
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:47
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:49
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:51
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:53
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:55
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:57
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:52:59
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:01
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User entered empty.	System	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User entered empty.	System	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:00
User entered empty.	System	16 Apr 2021 17:54:54

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:08
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:59:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 17:59:46
Data point term sent to Coder	System	16 Apr 2021 17:58:59
User entered 'LACTATED RINGERS'	Erica Osmundsen (b) (4) 	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:10
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:11
User entered 'WORSENING RIGHT KNEE OSTEOARTHRITIS'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:13
User entered '1000'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:15
User entered 'mL (mL)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:16
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:18
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:20
User entered 'CONTINUOUS'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:22
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:25
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:28
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:29
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:31
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:33
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User entered empty.	System	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User entered empty.	System	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:28
User entered empty.	System	16 Apr 2021 17:58:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:48:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 13:48:49
Data point term sent to Coder	System	16 Apr 2021 18:00:00
User entered 'SODIUM CHLORIDE 0.45%'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:40
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:41
User entered 'WORSENING OF RIGHT KNEE OSTEOARTHRITIS'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:44
User entered '100'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:47
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:49
User entered 'mL/hour'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:51
User entered 'other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:53
User entered 'continuous'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:55
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:57
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:53:58
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:00
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:02
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:04
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:05
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User entered empty.	System	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User entered empty.	System	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:32
User entered empty.	System	16 Apr 2021 17:59:41

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Apr 2021 11:09:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Apr 2021 11:09:56
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:54:10
Data point term sent to Coder	System	16 Apr 2021 18:02:03
User entered 'oxycodone (Roxicodone)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:12
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:17
User entered 'acute post-operative pain'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:21
User entered '5'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:22
User entered 'mg (mg)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:24
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:26
User entered 'as needed (PRN)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:28
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:29
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:31
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:33
User entered '12 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:35
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:37
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:39
User entered '26 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:41
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User entered empty.	System	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User entered empty.	System	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:37
User entered empty.	System	16 Apr 2021 18:01:02

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:46
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:02:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 18:02:52
Data point term sent to Coder	System	16 Apr 2021 18:02:08
User entered 'warfarin'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:48
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:50
User entered 'blood clot prophylaxis'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:52
User entered '5'	Erica Osmundsen (b) (4) 	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:55
User entered 'mg (mg)'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:57
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:54:59
User entered 'once daily (QD)'	Erica Osmundsen (b) (4) 	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:01
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:03
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:08
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:36
User entered '12 Feb 2021'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:39
User entered '0'	Erica Osmundsen (b) (4) 	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:40
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:42
User entered '29 Mar 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:55:44
User entered 'No (N)'	Erica Osmundsen (b) (4) 	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 18:01:39

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
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)	21 Apr 2021 09:27:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:27:06
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 16:56:04
Data point term sent to Coder	System	16 Apr 2021 18:07:15
User entered 'SPINAL ANESTHESIA'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:05
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:07
User entered 'WORSENING OF RIGHT KNEE OSTEOARTHRITIS'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:09
User entered 'UNK'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:11
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:13
User entered 'UNKNOWN'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:14
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:17
User entered empty.	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:19
User entered 'Other (OTHER)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:23
User entered 'INJECTION TO SUBARACHNOID CEREBROSPINAL FLUID SPACE'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:25
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:27
User entered '0'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:29
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:30
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:56:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered empty.	System	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered empty.	System	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:54
User entered empty.	System	16 Apr 2021 18:07:10

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIHEMORRHAGICS, ATC: ANTIFIBRINOLYTICS, ATC: AMINO ACIDS, PRODUCT: TRANEXAMIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:12:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:12:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:44:03
Data point term sent to Coder	System	19 Apr 2021 18:18:00
User entered 'TRANEXAMIC ACID'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:07
User entered 'Yes (Y)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:06
User entered 'SURGICAL PROPHYLAXIS (TO PREVENT BLOOD LOSS DUE TO ANTICOAGULANT USE)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:11
User entered 'I'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:13
User entered 'g (g)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:15
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:17
User entered 'once (ONCE)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:19
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:22
User entered 'Intravenous (INTRAVENOUS)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:23
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:25
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:29
User entered '0'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:30
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:32
User entered '11 Feb 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:34
User entered 'No (N)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User entered empty.	System	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User entered empty.	System	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:16:58
User entered empty.	System	19 Apr 2021 18:17:37

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:19:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 18:19:47
Data point term sent to Coder	System	19 Apr 2021 18:19:01
User entered 'ELIQUIS'	Erica Osmundsen (b) (4) (b) (4) (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:52
User entered 'No (N)'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:53
User entered 'CARDIAC ARRHYTHMIA'	Erica Osmundsen (b) (4) [REDACTED] [REDACTED]	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:55
User entered '5'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:57
User entered 'mg (mg)'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:44:58
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:00
User entered 'twice daily (BID)'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:02
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:05
User entered 'Oral (ORAL)'	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:07
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:10
User entered '30 Mar 2021'	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:11
User entered '0'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:13
User entered 'Yes (Y)'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:15
User entered empty.	Erica Osmundsen (b) (4)	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 18:45:17
User entered 'No (N)'	Erica Osmundsen (b) (4) 	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:43:30

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 18:18:23

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:43:30

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:20:25
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:05:56
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) Teresa Deese (b) (4)	02 Mar 2021 14:33:09
User closed query 'Source note= Voltaren Gel for Knee surgery, UnNov2020. Please verify date and confirm date of knee surgery. Please document the details in source and add to AE log/SAE if appropriate. ' (Site from CRA).	(b) (4), (b) (6)	21 Jan 2021 16:05:02
Query 'Source note= Voltaren Gel for Knee surgery, UnNov2020. Please verify date and confirm date of knee surgery. Please document the details in source and add to AE log/SAE if appropriate. ' answered with 'KNEE SURGERY PRIOR TO SCREENING (APRIL 2020)' (Site from CRA).	Erica Osmundsen (b) (4)	09 Dec 2020 21:14:06
User opened query 'Source note= Voltaren Gel for Knee surgery, UnNov2020. Please verify date and confirm date of knee surgery. Please document the details in source and add to AE log/SAE if appropriate. ' (Site from CRA).	(b) (4), (b) (6)	09 Dec 2020 20:39:32
User entered 'No (N)'	Erica Osmundsen (b) (4)	20 Oct 2020 21:51:45

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:30

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:24
User entered '11 Feb 2021'	Teresa Deese (b) (4)	02 Mar 2021 14:33:35

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:30

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:06:20
	(b) (4), (b) (6)	
User closed query 'Please verify hospital records have been requested.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:14:24
Signature has been broken.	Erica Osmundsen (b) (4)	16 Apr 2021 18:10:41
User entered 'RIGHT KNEE ARTHROPLASTY (RIGHT TOTAL KNEE REPLACEMENT)' reason for change: Data Entry Error	Erica Osmundsen (b) (4)	16 Apr 2021 18:10:41
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
	(b) (4)	
Query 'Please verify hospital records have been requested.' answered with 'done' (Site from CRA).	Teresa Deese (b) (4)	07 Apr 2021 16:21:55
DataPoint Un-verified.	(b) (4), (b) (6)	06 Apr 2021 16:20:03
	(b) (4), (b) (6)	
User opened query 'Please verify hospital records have been requested.' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 16:20:01
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 16:19:24
User entered 'right knee surgery- outpatient'	Teresa Deese (b) (4)	02 Mar 2021 14:33:35

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:30

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:24
User entered 'Adverse Event (AE)'	Teresa Deese (b) (4)	02 Mar 2021 14:33:35

US3202217

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:43:30

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	09 Apr 2021 15:42:04
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 16:19:24
User entered empty.	Teresa Deese (b) (4)	02 Mar 2021 14:33:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'USA-US128-2021-MRNA-1273-P301000020'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Mark'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'McKenzie'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 20:12:27
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered 'US'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 15:26:05
User entered '2'	System	23 Apr 2021 20:12:44
User entered '1'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'USA-US128-2021-MRNA-1273-P301000020'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Mark'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'McKenzie'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 20:12:27
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered 'US'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 15:26:05
User entered '2'	System	23 Apr 2021 20:12:44
User entered '1'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered '19/Apr/2021 15:59'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:43:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 20:12:27
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'USA-US128-2021-MRNA-1273-P301000020'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Mark'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'McKenzie'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 20:12:27
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered 'US'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 15:26:05
User entered '2'	System	23 Apr 2021 20:12:44
User entered '1'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:01:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:19:24
User entered '23/Apr/2021 16:12'	System	23 Apr 2021 20:12:44

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:43:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	28 Apr 2021 07:01:50
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 17:19:24
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 20:12:44

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'USA-US128-2021-MRNA-1273-P301000020'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Yes (Y)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'No (N)'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'Mark'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:59:27
User entered 'McKenzie'	System	19 Apr 2021 13:36:35

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 20:12:27
User signature succeeded.	Mark McKenzie (b) (4)	22 Apr 2021 17:58:11
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 17:06:52
User entered 'US'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form

Generated On: 09 Jun 2021 15:43:30

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	03 May 2021 15:26:05
User entered '2'	System	23 Apr 2021 20:12:44
User entered '1'	System	19 Apr 2021 15:59:33

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:30

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '03/May/2021 08:26'	System	03 May 2021 15:26:05

US3202217

Folder: SAE USA-US128-2021-MRNA-1273-P301000020

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:43:30

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered 'I'	(b) (4), (b) (6)	03 May 2021 15:26:05