

US3402212 (Prod: Meridian Clinical Research, LLC)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:22:36

All time stamps listed in this document are displayed in GMT

US3402212

Form: Participant Creation

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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[Participant ID](#)

US3402212

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

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US3402212

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 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

US3402212

Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Date of Birth (MMM yyyy)	(b) (6) 1941
Age	79
Age Units	YEARS
Age (Derived)	79
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3402212

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Date of Informed Consent ( <i>dd MMM yyyy</i> )	4 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input 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

US3402212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3402212

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

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Were any significant conditions reported?

Yes ☒

No ☐

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US3402212

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	TYPE II DIABETES
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)	_____



US3402212

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	MODERATE OBESITY
Start date (dd MMM yyyy)	UN UNK 1953
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 1953
Start Year (derived)	1953
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3402212

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	OSTEOPOROSIS
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)	

US3402212

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	DEGENERATIVE JOINT DISEASE
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)	_____

US3402212

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	HYPERTENSION
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)	_____

US3402212

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	BILATERAL FOOT EDEMA
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)	_____

US3402212

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	DIABETIC NEUROPATHY
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)	

US3402212

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	OSTEOARTHRITIS, SPINE
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)	_____

US3402212

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	HYPERLIPIDEMIA
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)	



US3402212

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3402212

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	RESTLESS LEG SYNDROME
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)	_____

US3402212

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Condition	BACK SPASMS
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)	_____

US3402212

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	4 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:02 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:02
Height ( <i>xxx.x</i> )	163.0 cm
Weight ( <i>xxx.x</i> )	98.6 kg
BMI ( <i>xxx.x</i> )	37.11092 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3402212

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 AUG 2020

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

US3402212

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*) 4 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 1980

Date of last menstruation unknown False

US3402212

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

US3402212

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

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



US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184531

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 ☒

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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)	4 AUG 2020
Time of assessment (00:00-23:59)	09:02 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 09:02
Temperature (xxx.x)	36.3 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)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 AUG 2020
Time of assessment (00:00-23:59)	10:45 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 10:45
Temperature (xxx.x)	35.0 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402212

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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.*

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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) 4 AUG 2020

What was the treatment time? (00:00-23:59) 10:05 (24 HR)

Treatment Date and Time (derived) 4 AUG 2020 10:05

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

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 AUG 2020
Collection time (00:00-23:59)	09:27 (24 HR)
Collection date and time (derived)	4 AUG 2020 09:27



US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)			4 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:30	4 AUG 2020 09:30
Nasopharyngeal Swab 2	No		

US3402212

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**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

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 10:37

PC Open Date & Time

04 AUG 2020 10:25

PC Close Date & Time

04 AUG 2020 12:55

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.4 °F

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

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

PC Time Stamp	04 AUG 2020 20:22
PC Open Date & Time	04 AUG 2020 13:50
PC Close Date & Time	05 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 20:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 21:02

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 20:26

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**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

97.5 °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

08 AUG 2020 22:13

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59



US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

09 AUG 2020 19:33

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 20:59

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**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

04 AUG 2020 10:38

PC Open Date & Time

04 AUG 2020 10:25

PC Close Date & Time

04 AUG 2020 12:55

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 AUG 2020 13:50

PC Close Date & Time

05 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**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

06 AUG 2020 21:04

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**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

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**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

09 AUG 2020 19:35

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**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

10 AUG 2020 21:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**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 ☐

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 10:39
PC Open Date & Time	04 AUG 2020 10:25
PC Close Date & Time	04 AUG 2020 12:55

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**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 ☐

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 AUG 2020 13:50

PC Close Date & Time

05 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

54 of 2777

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Yes ☐

PC Time stamp

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

56 of 2777

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 21:04
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**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 ☒

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 20:28
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

60 of 2777

EAB) (1725)

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 22:14
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

62 of 2777

EAB) (1725)

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:34
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**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 ☒

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

US3402212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:04

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 18 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:04

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:04

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 SEP 2020
Time of assessment (00:00-23:59)	07:27 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 07:27
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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)	4 SEP 2020
Time of assessment (00:00-23:59)	08:37 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 08:37
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3402212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 08:04 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 08:04

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

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	07:45 (24 HR)
Collection date and time (derived)	4 SEP 2020 07:45

US3402212

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	07:42	4 SEP 2020 07:42
Nasopharyngeal Swab 2	No		

US3402212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐  
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

04 SEP 2020 08:24

PC Close Date & Time

04 SEP 2020 10:54

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**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 97.0 °F

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

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

PC Time Stamp	04 SEP 2020 20:14
PC Open Date & Time	04 SEP 2020 11:49
PC Close Date & Time	05 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**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

05 SEP 2020 20:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

07 SEP 2020 20:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 20:18

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 20:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 20:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

04 SEP 2020 08:24

PC Close Date & Time

04 SEP 2020 10:54

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**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

04 SEP 2020 20:15

PC Open Date & Time

04 SEP 2020 11:49

PC Close Date & Time

05 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**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

05 SEP 2020 20:13

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**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

06 SEP 2020 19:58

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**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

07 SEP 2020 20:12

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**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

08 SEP 2020 20:19

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**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

09 SEP 2020 20:20

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**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

10 SEP 2020 20:22

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**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 ☐

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

04 SEP 2020 08:24

PC Close Date & Time

04 SEP 2020 10:54

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**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 ☐

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 20:16
PC Open Date & Time	04 SEP 2020 11:49
PC Close Date & Time	05 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:14
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:59
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 20:13
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

106 of 2777

EAB) (1725)

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 20:19
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 20:21
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 20:22
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59



US3402212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☒

Comments

LEFT 3 VOICE MAIL MESSAGES  
WITH NO CALL BACK

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:35

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	13 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	09:12 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 09:12
Temperature ( <i>xxx.x</i> )	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	71 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3402212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

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.*

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 OCT 2020
Collection time (00:00-23:59)	09:15 (24 HR)
Collection date and time (derived)	13 OCT 2020 09:15

US3402212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 17:12:36

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

Patient Cloud Close Date & Time

08 OCT 2020 23:59

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 16:46:42

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59



US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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°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="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 21:29:41
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 08:30:08

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 09:40:28

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

29 NOV 2020 07:01:32

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 09:56:47

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 DEC 2020 07:25:03

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 09:57:18

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

27 DEC 2020 16:59:22

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

03 JAN 2021 08:49:08

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

10 JAN 2021 09:58:57

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 JAN 2021 07:36:49
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

24 JAN 2021 08:37:33

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 FEB 2021 08:00:33

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	07 FEB 2021 13:43:12
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 12:47:40
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

21 FEB 2021 14:28:57

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

28 FEB 2021 18:03:22

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 18:10:21

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 MAR 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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25 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAR 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 243

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	12 APR 2021 23:26:37
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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

18 APR 2021 09:08:03

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	25 APR 2021 19:28:33
Patient Cloud Open Date & Time	22 APR 2021 00:01
Patient Cloud Close Date & Time	26 APR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 22:23:40

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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06 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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03 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUN 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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05 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	19 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	23 AUG 2021 23:59
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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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04 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59
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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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18 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 NOV 2021 23:59
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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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02 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 DEC 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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06 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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27 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 FEB 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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17 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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03 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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17 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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21 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 APR 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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 <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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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°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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

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"/>

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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11 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59



US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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25 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 AUG 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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01 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2022 23:59
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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**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 ☐

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59
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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 OCT 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

DAY 796

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

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[Patient Cloud Open Date & Time](#)

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06 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3402212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:22:36

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 18:04:16

US3402212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 08 Mar 2021 22:20:38

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3402212

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 08 Mar 2021 22:20:38

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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

Visit date (dd MMM yyyy)	2 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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US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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) \_\_\_\_\_

US3402212

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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.*

US3402212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

2 MAR 2021 09:15

US3402212

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3402212

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3402212**

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

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

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*

**US3402212**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



**US3402212**

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

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 17:22:36**

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

**US3402212**

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

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

**Generated On: 09 Jun 2021 17:22:36**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3402212

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

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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

---

Visit date (dd MMM yyyy)	18 JAN 2021
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---

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

---

Folder OID	UNBLND_DECIDE
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US3402212

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

Form: Unblinding

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Date of updated informed consent (dd MMM yyyy) 06 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3402212

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

14:50 (24 HR)

Collection date and time (derived)

18 JAN 2021 14:50

US3402212

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

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

Collection date (dd MMM yyyy)	18 JAN 2021
-------------------------------	-------------

Collection time (00:00 - 23:59)	14:52
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Collection Date and Time (derived)	18 JAN 2021 14:52
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US3402212

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 14 Mar 2021 14:39:45

Generated On: 09 Jun 2021 17:22:36

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

AEID	USA-US059-2020-MRNA-1273-P30 1000001
Adverse event	WORSENING SPINAL STENOSIS
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	29 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	25 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

335 of 2777



US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

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SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE. WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS GREATER THAN 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, SUBJECT ALSO HAD CHEST X-RAY WHICH WAS NEGATIVE, A MRI OF LUMBAR SPINE THAT SHOWED THE WORSENING OF SPINAL STENOSIS. SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. SUBJECT HAD CONSULT WITH ORTHOPEDIC SURGEON FOR A PLANNED SURGERY. THIS TOOK PLACE 22SEP2020. THE FOLLOWING PROCEDURES WERE PERFORMED, POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

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ILIAC CREST BONE MARROW  
ASPIRATION AND  
APPLICATION OF 30ML OF  
BETA TRICALCIUM PHOSPHATE  
AND LOCAL AUTOLOGOUS  
BONE. SUBJECT 7 DAYS IN THE  
HOSPITAL POST OPERATIVELY.  
SUBJECT ALSO HAD COVID  
TESTING PRIOR TO SURGERY  
THAT WAS NEGATIVE.  
SUBJECT ALSO HAD ANOTHER  
LUMBAR SPINE X-RAY THAT  
CONFIRMED PRIOR LUMBAR  
XRAY THAT SHOWED  
WORSENING OF SPINAL  
STENOSIS.

---

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

---

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

339 of 2777

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

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

US3402212

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

AEID

Adverse event

KIDNEY STONES

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)

13 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 MAR 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

PRODUCTION RELEASE (v12.003

341 of 2777

EAB) (1725)

US3402212

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 22:58:17

Generated On: 09 Jun 2021 17:22:36

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	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)	0
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 23:31:27

Generated On: 09 Jun 2021 17:22:36

---

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

Yes ☒

No ☐

---

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

---



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication PRAMIPREXOLE

Prophylaxis Yes ☐  
No ☒

Indication RESTLESS LEG SYNDROME

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

344 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication CINNAMON

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

346 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication ALENDRONATE SODIUM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPOROSIS

Dose per administration 35

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

348 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication VITAMIN D3

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 2000

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)

350 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication LASIX

Prophylaxis Yes ☐  
No ☒

Indication EDEMA BILATERAL FEET

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

352 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

354 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication SEMAGLUTIDE

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

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)

356 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input checked="" type="radio"/>
	804	<input type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

358 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

360 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

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 ☐

PRODUCTION RELEASE (v12.003

362 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication GABAPENTIN

Prophylaxis Yes ☐  
No ☒

Indication DIABETIC NEUROPATHY

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 ☐

PRODUCTION RELEASE (v12.003

364 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication MELOXICAM

Prophylaxis Yes ☐  
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

366 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication CARVEDILOL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 6.25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

368 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication VITAMIN C

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

370 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication VITAMIN E

Prophylaxis Yes ☒  
No ☐

Indication DIETARY SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

372 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication PAIN ASSOCIATED WITH  
WORSENING SPINAL STENOSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

374 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

376 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication DEXAMETHASONE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 4

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

378 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication DONEPEZIL

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

380 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication HEPARIN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 5,000

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

382 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)		23 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication INSULIN ASPART

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 100/4

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

If dose unit is Other, specify IU/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

384 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 10

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

If dose unit is Other, specify MEQ

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

386 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication VALSARTAN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 160

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

388 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

Q4H

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

PRODUCTION RELEASE (v12.003

390 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication DEXTROSE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 25/50

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

If dose unit is Other, specify G/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

392 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication GLUCAGON

Prophylaxis Yes ☐  
No ☒

Indication TYPE II DIABETES

Dose per administration 1/1

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

394 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication MAGNESIUM HYDROXIDE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 30

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

396 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 2/1

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify Q4H

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

PRODUCTION RELEASE (v12.003

398 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify Q4H

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

PRODUCTION RELEASE (v12.003

400 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication OXYCODONE IR

Prophylaxis Yes ☐  
No ☒

Indication WORSENING SPINAL STENOSIS

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

402 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication CHLORTHALIDONE

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 ☐

PRODUCTION RELEASE (v12.003

404 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)		07 DEC 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"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication DHLORTHALI

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

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 ☐

PRODUCTION RELEASE (v12.003

406 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication KIDNEY STONES

Dose per administration 875

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

408 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	16 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)	26 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication TIZANIDINE

Prophylaxis Yes ☐  
No ☒

Indication KIDNEY STONES

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

410 of 2777

EAB) (1725)

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	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)	16 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)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication MEDROL PREDNISONE

Prophylaxis Yes ☐  
No ☒

Indication SCIATIC NERVE PAIN

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

412 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	8 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	12 APR 2021	
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"/>	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication TRAMADOL

Prophylaxis Yes ☐  
No ☒

Indication SCIATIC NERVE PAIN

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

414 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		01 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 APR 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"/>



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication SCIATIC NERVE PAIN

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

416 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 15 Apr 2021 00:03:40

Generated On: 09 Jun 2021 17:22:36

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

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 23:31:27

Generated On: 09 Jun 2021 17:22:36

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 00:03:42

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 AUG 2020	MRI LUMBAR SPINE	Adverse Event	
23 AUG 2020	CHEST XRAY	Adverse Event	
23 AUG 2020	LUMBAR SPINE XRAY	Adverse Event	
22 SEP 2020	POSTERIOR SPINAL FUSION L2, L3, L4, L5,	Adverse Event	
22 SEP 2020	WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY L2-L5 WITH DECOMPRESSION OF L 3, L4, L5 NERVE ROOT.	Adverse Event	
22 SEP 2020	VERTEBROPLASTY L2, L3, L4, L5	Adverse Event	
22 SEP 2020	LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE	Adverse Event	
22 SEP 2020	LUMBAR SPINE XRAY	Adverse Event	
25 AUG 2020	COMPLETE BLOOD COUNT	Adverse Event	
25 AUG 2020	COMPLETE METABOLIC PROFILE	Adverse Event	
22 SEP 2020	COMPLETE BLOOD COUNT	Adverse Event	
23 SEP 2020	COMPLETE BLOOD COUNT	Adverse Event	
24 SEP 2020	COMPLETE BLOOD COUNT	Adverse Event	
25 SEP 2020	COMPLETE BLOOD COUNT	Adverse Event	

PRODUCTION RELEASE (v12.003 EAB) (1725)

419 of 2777

US3402212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:22:36

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

US3402212

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:22:36

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 ☐

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/AUG/2020 10:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	14/SEP/2020 15:43
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

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/NOV/2020 13:44
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

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 22:49:24

Generated On: 09 Jun 2021 17:22:36

SAEID	USA-US059-2020-MRNA-1273-P301000001
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	FRANK
Investigator's Last Name	EDER
Site Address: Street	1290 UPPER FRONT STREET
Site Address: City	BINGHAMTON
Site Address: State	NY
Site Address: Postal Code	13901
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:27
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

US3402212 (Prod: Meridian Clinical Research, LLC)

**US3402212**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:22:36**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'US3402212'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:19:27

**US3402212**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:22:17

US3402212

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:19:27



**US3402212**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[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 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:22:17

**US3402212**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'SCRN'	System	05 Aug 2020 13:22:17

US3402212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered (b) (6) 1941' reason for change: Data Entry Error	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	26 Aug 2020 09:24:14
User entered '(b) (6)1941'	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:19:28

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '79'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'YEARS'	System	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '79'	System	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Female (F)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13



**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'I'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:22:36

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13



**US3402212**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:22:36**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:13

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Aug 2020'	System	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2020'	System	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:28



**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:28

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:19:27

**US3402212**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:22:36**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'I'	System	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:22:36

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:22:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:23:30

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 13:26:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 13:26:12
Data point term sent to Coder	System	05 Aug 2020 13:25:07
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:13



**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2010'	System	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2010'	System	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:24:13

**US3402212**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	14 Aug 2020 09:45:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 09:45:18
Data point term sent to Coder	System	05 Aug 2020 13:25:07
User entered 'MODERATE OBESITY'	Tarin Gordon (b) (4)	05 Aug 2020 13:24:40
	(b) (4)	



**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 1953'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 1953'	System	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '1953'	System	05 Aug 2020 13:24:40

**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:24:40



**US3402212**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Aug 2020 13:26:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:26:12
Data point term sent to Coder	System	05 Aug 2020 13:25:08
User entered 'OSTEOPOROSIS'	Tarin Gordon (b) (4)	05 Aug 2020 13:25:01
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:25:01



**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:01

**US3402212**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Per DM CLR: Please specify the location where the DEGENERATE JOINT DISEASE is affecting. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:00:36
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Degenerative joint disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:42:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:42:49
Data point term sent to Coder	System	03 Oct 2020 18:41:55
Query 'Per DM CLR: Please specify the location where the DEGENERATE JOINT DISEASE is affecting. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 18:41:45
' answered with 'updated' (Site from DM).		
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 18:41:33
User entered 'DEGENERATIVE JOINT DISEASE' reason for change: Per Query Resolution	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 18:41:33
User opened query 'Per DM CLR: Please specify the location where the DEGENERATE JOINT DISEASE is affecting. Review and update medical history diagnosis as appropriate and ensure update to MH is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	21 Sep 2020 20:55:47
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Degenerative joint disease - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:00:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:00:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

491 of 2777

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Aug 2020 13:26:10
User entered 'DEGENERATE JOINT DISEASE'	Tarin Gordon (b) (4)	05 Aug 2020 13:25:22
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:22



**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:22

**US3402212**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	05 Aug 2020 13:27:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:27:14
Data point term sent to Coder	System	05 Aug 2020 13:26:12
User entered 'HYPERTENSION'	Tarin Gordon (b) (4)	05 Aug 2020 13:25:40
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:40



**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:40

**US3402212**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:25:40



US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Foot edema - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:12:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 17:12:57
Data point term sent to Coder	System	05 Aug 2020 13:26:14
User entered 'BILATERAL FOOT EDEMA'	Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:26:07



**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:26:07

**US3402212**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:29:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:29:20
Data point term sent to Coder	System	05 Aug 2020 13:28:16
User entered 'DIABETIC NEUROPATHY'	Tarin Gordon (b) (4)	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:27:36



**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:27:36

**US3402212**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:43:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:43:17
Data point term sent to Coder	System	05 Aug 2020 13:28:17
User entered 'OSTEOARTHRITIS, SPINE'	Tarin Gordon (b) (4)	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:01



**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:28:01

**US3402212**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
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.	(b) (4) (b) (4) Coder Import (b) (4)	05 Aug 2020 13:30:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 13:30:18
Data point term sent to Coder	System	05 Aug 2020 13:29:20
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:19



**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:28:19

**US3402212**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:28:19



US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	(b) (4) (b) (4) Coder Import (b) (4)	05 Aug 2020 13:31:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Aug 2020 13:31:19
Data point term sent to Coder	System	05 Aug 2020 13:30:21
User entered 'POST-MENOPAUSAL'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Per DM CLR: Please note, Start date of MH = UNK 1981. However, Post-menopausal date recorded in Childbearing ecf is UNK 1980. Review and reconcile dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4)	07 Oct 2020 15:00:14
Query 'Per DM CLR: Please note, Start date of MH = Jennifer Molstead UNK 1981. However, Post-menopausal date recorded in Childbearing ecf is UNK 1980. Review and reconcile dates as appropriate. Otherwise, clarify. ' answered with 'updated' (Site from DM).	(b) (4)	03 Oct 2020 18:42:49
User entered 'UN UNK 1980' reason for change: Per Jennifer Molstead Query Resolution	(b) (4)	03 Oct 2020 18:42:38
User opened query 'Per DM CLR: Please note, Start date of MH = UNK 1981. However, Post-menopausal date recorded in Childbearing ecf is UNK 1980. Review and reconcile dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:56:46
User entered 'UN UNK 1981'	Tarin Gordon (b) (4)	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 1980'	System	03 Oct 2020 18:42:38
User entered 'Jan 1981'	System	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '1980'	System	03 Oct 2020 18:42:38
User entered '1981'	System	05 Aug 2020 13:30:04



**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:30:04

**US3402212**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Restless legs syndrome, LLT: Restless leg syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:33:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Aug 2020 13:33:21
Data point term sent to Coder	System	05 Aug 2020 13:31:21
User entered 'RESTLESS LEG SYNDROME'	Tarin Gordon (b) (4)	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 2015'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:30:35



**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:30:35

**US3402212**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:22:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 13:28:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	03 Dec 2020 13:28:02
Data point term sent to Coder	System	03 Dec 2020 13:26:36
User entered 'back spasms'	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'un UNK 2015'	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44



**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	Jennifer Molstead (b) (4)	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'Jan 2015'	System	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '2015'	System	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	03 Dec 2020 13:25:44

**US3402212**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered empty.	System	03 Dec 2020 13:25:44

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58



**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:02'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered '4 Aug 2020 09:02'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '163.0' cm	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
DataPoint set to visible.	(b) (4) System	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '98.6' kg	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
DataPoint set to visible.	(b) (4) System	04 Aug 2020 14:11:34

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
Amendment Manager: User entered '37.11092'	System	16 Sep 2020 23:42:07
User entered '37.1'	System	05 Aug 2020 13:41:58
DataPoint set to visible.	System	04 Aug 2020 14:11:34

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'kg/m2'	System	05 Aug 2020 13:41:58
DataPoint set to visible.	System	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered '36.3' C	Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered 'Oral (Oral)'	Tammy Kohn (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	



US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered '64'	Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'bpm'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered '16'	Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'breaths/min'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered '130'	Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'mmHg'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:36:06
User entered '74'	Tarin Gordon (b) (4)	05 Aug 2020 13:41:58
	(b) (4)	



US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User entered 'mmHg'	System	05 Aug 2020 13:41:58

**US3402212**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03

**US3402212**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:21

US3402212

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	06 Sep 2020 12:39:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 12:18:01
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:21

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54



US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:22:36

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'UN UNK 1980'	Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

**US3402212**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:22:36**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36



US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36



US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

**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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

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)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'I'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36



US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '0'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:22:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 18:46:03
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:36

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 13:43:49

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Clinic (Clinic)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:43:49

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'VISIT1'	System	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:25:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 01:53:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:53:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 13:25:04
User entered '184531' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:25:04



US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 13:25:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:46:04

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:22:36**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:46:04

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:22:36**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:22:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '163.0' cm	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '98.6' kg	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	



US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '163.0' cm	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '98.6' kg	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Pre-Dose (PREDOSE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:02'	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Aug 2020 09:02'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '36.3' C	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	



**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '64'	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'bpm'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '16'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'breaths/min'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '130'	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	05 Aug 2020 13:47:49



US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '74'	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '163.0' cm	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:22:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Dec 2020 16:35:46
User entered '98.6' kg	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Post-Dose (POSTDOSE)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	05 Aug 2020 13:47:49
	Tarin Gordon (b) (4)	
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:26:37
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with '30 MIN' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:02
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 13:47:49
User entered '10:45'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49



**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Aug 2020 10:45'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Per CDM: Thank you for your response. However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 08:50:31
Query 'Per CDM: Thank you for your response. However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate. ' answered with 'This is not clinically significant' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 18:43:53
User closed query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 06:01:28
User opened query 'Per CDM: Thank you for your response. However please advice if the out of range value is CS/NCS. If CS, please report as AE as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 06:01:22
Query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' answered with 'CORRECT AS IS' (Site from DM).	Traci Hull (b) (4) (b) (4)	23 Sep 2020 14:56:56
User opened query 'Per CDM: Per previous query, please confirm if this result should be considered clinically significant or not.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 14:55:56
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	18 Sep 2020 14:55:29
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'Temperature is correct. no cold drinks prior to taking.' (Site from System).	Tammy Kohn (b) (4) (b) (4)	17 Sep 2020 12:28:56

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User opened query 'Temperature reported is out of range &lt; 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). User entered '35.0' C	System  Tarin Gordon (b) (4) (b) (4)	16 Sep 2020 23:42:07  05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Oral (Oral)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '66'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'bpm'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '16'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:47:49



US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'breaths/min'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '124'	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '68'	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	18 Sep 2020 16:57:24
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	05 Aug 2020 13:48:12
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:22:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty; reason for change Data Entry Error	(b) (4)	18 Sep 2020 16:57:24
User entered '4 Aug 2020'	Tammy Kohn (b) (4)	05 Aug 2020 13:48:12
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:58



**US3402212**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:22:36**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Tarin Gordon (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '10:05'	(b) (4)	
	Tarin Gordon (b) (4)	04 Aug 2020 14:11:58
	(b) (4)	

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Aug 2020 10:05'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'ONCE'	System	04 Aug 2020 14:11:58



US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:48:32

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:48:32

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:27'	(b) (4)	
	Tarin Gordon (b) (4)	05 Aug 2020 13:48:32
	(b) (4)	

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Aug 2020 09:27'	System	05 Aug 2020 13:48:32

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:22:36**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Aug 2020'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:48:52



**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:30'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Aug 2020 09:30'	System	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:48:52

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered empty.	System	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	05 Aug 2020 13:48:57
	Tarin Gordon (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '1'	System	05 Aug 2020 13:48:57



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:36:49', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '046490ac-ff52-4564-8ea3-935bd24ee0f0'	System	04 Aug 2020 14:37:31
User entered 'Yes (Y)'	System	04 Aug 2020 14:37:31

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:37:02', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '046490ac-ff52-4564-8ea3-935bd24ee0f0'	System	04 Aug 2020 14:37:31
User entered '95.1'	System	04 Aug 2020 14:37:31

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:37:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '046490ac-ff52-4564-8ea3-935bd24ee0f0'	System	04 Aug 2020 14:37:31
User entered 'No (N)'	System	04 Aug 2020 14:37:31

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:37:24', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '046490ac-ff52-4564-8ea3-935bd24ee0f0'	System	04 Aug 2020 14:37:31
User entered '04 Aug 2020 10:37'	System	04 Aug 2020 14:37:31

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 10:25'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 12:55'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T20:22:29', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bde1ed4d-d73b-4e2d-b0df-afe5e934979c'	System	05 Aug 2020 00:23:02
User entered 'Yes (Y)'	System	05 Aug 2020 00:23:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T20:22:40', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bde1ed4d-d73b-4e2d-b0df-afe5e934979c' User entered '98.4'	System	05 Aug 2020 00:23:02
	System	05 Aug 2020 00:23:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T20:22:46', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bde1ed4d-d73b-4e2d-b0df-afe5e934979c'	System	05 Aug 2020 00:23:02
User entered 'No (N)'	System	05 Aug 2020 00:23:02

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T20:22:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bde1ed4d-d73b-4e2d-b0df-afe5e934979c'	System	05 Aug 2020 00:23:02
User entered '04 Aug 2020 20:22'	System	05 Aug 2020 00:23:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 13:50'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 2'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-05T20:26:09', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'beb1b641-2f87-4ccf-8649-3cdf8e0ea01f'	System	06 Aug 2020 00:26:40
User entered 'Yes (Y)'	System	06 Aug 2020 00:26:40



US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-05T20:26:19', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'beb1b641-2f87-4ccf-8649-3cdf8e0ea01f' User entered '97.6'	System	06 Aug 2020 00:26:40
	System	06 Aug 2020 00:26:40

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-05T20:26:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'beb1b641-2f87-4ccf-8649-3cdf8e0ea01f'	System	06 Aug 2020 00:26:40
User entered 'No (N)'	System	06 Aug 2020 00:26:40

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-05T20:26:35', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'beb1b641-2f87-4ccf-8649-3cdf8e0ea01f' User entered '05 Aug 2020 20:26'	System	06 Aug 2020 00:26:40
	System	06 Aug 2020 00:26:40

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 3'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:02:10', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '41524172-79fb-4315-876b-4d3d6fa3d6d4'	System	07 Aug 2020 01:02:41
User entered 'Yes (Y)'	System	07 Aug 2020 01:02:41

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:02:19', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '41524172-79fb-4315-876b-4d3d6fa3d6d4'	System	07 Aug 2020 01:02:41
User entered '98.6'	System	07 Aug 2020 01:02:41



US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:02:24', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '41524172-79fb-4315-876b-4d3d6fa3d6d4'	System	07 Aug 2020 01:02:41
User entered 'No (N)'	System	07 Aug 2020 01:02:41

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:02:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '41524172-79fb-4315-876b-4d3d6fa3d6d4'	System	07 Aug 2020 01:02:41
User entered '06 Aug 2020 21:02'	System	07 Aug 2020 01:02:41

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 4'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:26:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '99410b22-d1b7-4559-a935-c5ea0a6ea288'	System	08 Aug 2020 00:26:43
User entered 'Yes (Y)'	System	08 Aug 2020 00:26:43

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:26:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '99410b22-d1b7-4559-a935-c5ea0a6ea288'	System	08 Aug 2020 00:26:43
User entered '98.6'	System	08 Aug 2020 00:26:43

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:26:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '99410b22-d1b7-4559-a935-c5ea0a6ea288'	System	08 Aug 2020 00:26:43
User entered 'No (N)'	System	08 Aug 2020 00:26:43



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:26:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '99410b22-d1b7-4559-a935-c5ea0a6ea288'	System	08 Aug 2020 00:26:43
User entered '07 Aug 2020 20:26'	System	08 Aug 2020 00:26:43

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 5'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:12:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'adca76da-bd5d-4763-a0a3-fc4935439282'	System	09 Aug 2020 02:13:27
User entered 'Yes (Y)'	System	09 Aug 2020 02:13:27

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'adca76da-bd5d-4763-a0a3-fc4935439282'	System	09 Aug 2020 02:13:27
User entered '97.5'	System	09 Aug 2020 02:13:27

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:06', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'adca76da-bd5d-4763-a0a3-fc4935439282'	System	09 Aug 2020 02:13:27
User entered 'No (N)'	System	09 Aug 2020 02:13:27

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:20', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'adca76da-bd5d-4763-a0a3-fc4935439282'	System	09 Aug 2020 02:13:27
User entered '08 Aug 2020 22:13'	System	09 Aug 2020 02:13:27



US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 6'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:33:28', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f91745ce-45a6-4f05-b063-41a542bee807'	System	09 Aug 2020 23:34:02
User entered 'Yes (Y)'	System	09 Aug 2020 23:34:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:33:40', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f91745ce-45a6-4f05-b063-41a542bee807'	System	09 Aug 2020 23:34:02
User entered '98.4'	System	09 Aug 2020 23:34:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:33:45', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f91745ce-45a6-4f05-b063-41a542bee807'	System	09 Aug 2020 23:34:02
User entered 'No (N)'	System	09 Aug 2020 23:34:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:33:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f91745ce-45a6-4f05-b063-41a542bee807'	System	09 Aug 2020 23:34:02
User entered '09 Aug 2020 19:33'	System	09 Aug 2020 23:34:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:11:58



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 7'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:56:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '6f0991f6-8907-499f-9190-9f4cc25461a4'	System	11 Aug 2020 00:59:48
User entered 'Yes (Y)'	System	11 Aug 2020 00:59:48

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '6f0991f6-8907-499f-9190-9f4cc25461a4'	System	11 Aug 2020 00:59:48
User entered '98.3'	System	11 Aug 2020 00:59:48

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '6f0991f6-8907-499f-9190-9f4cc25461a4'	System	11 Aug 2020 00:59:48
User entered 'No (N)'	System	11 Aug 2020 00:59:48

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:40', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '6f0991f6-8907-499f-9190-9f4cc25461a4'	System	11 Aug 2020 00:59:48
User entered '10 Aug 2020 20:59'	System	11 Aug 2020 00:59:48

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:09', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '51682831-b024-4683-8df9-bf728a633ddf'	System	04 Aug 2020 14:38:52
User entered 'None (1)'	System	04 Aug 2020 14:38:52

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '51682831-b024-4683-8df9-bf728a633ddf'	System	04 Aug 2020 14:38:52
User entered 'No (N)'	System	04 Aug 2020 14:38:52

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:17', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '51682831-b024-4683-8df9-bf728a633ddf'	System	04 Aug 2020 14:38:52
User entered 'No (N)'	System	04 Aug 2020 14:38:52

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:33', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '51682831-b024-4683-8df9-bf728a633ddf'	System	04 Aug 2020 14:38:52
User entered 'None (1)'	System	04 Aug 2020 14:38:52

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:44', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '51682831-b024-4683-8df9-bf728a633ddf'	System	04 Aug 2020 14:38:52
User entered '04 Aug 2020 10:38'	System	04 Aug 2020 14:38:52

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 10:25'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 12:55'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 13:50'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 2'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 3'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '47a5c7ab-44ee-4dbd-9f9f-9efc3d54674d'	System	07 Aug 2020 01:05:03
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 01:05:03

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:30', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '47a5c7ab-44ee-4dbd-9f9f-9efc3d54674d'	System	07 Aug 2020 01:05:03
User entered 'No (N)'	System	07 Aug 2020 01:05:03

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '47a5c7ab-44ee-4dbd-9f9f-9efc3d54674d'	System	07 Aug 2020 01:05:03
User entered 'No (N)'	System	07 Aug 2020 01:05:03



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:44', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '47a5c7ab-44ee-4dbd-9f9f-9efc3d54674d'	System	07 Aug 2020 01:05:03
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 01:05:03

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:57', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '47a5c7ab-44ee-4dbd-9f9f-9efc3d54674d'	System	07 Aug 2020 01:05:03
User entered '06 Aug 2020 21:04'	System	07 Aug 2020 01:05:03

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 4'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 5'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 6'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:57', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0597d47d-7f7b-4353-b222-e2a08d4c06f4'	System	09 Aug 2020 23:35:23
User entered 'None (1)'	System	09 Aug 2020 23:35:23

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:35:01', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0597d47d-7f7b-4353-b222-e2a08d4c06f4'	System	09 Aug 2020 23:35:23
User entered 'No (N)'	System	09 Aug 2020 23:35:23

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:35:06', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0597d47d-7f7b-4353-b222-e2a08d4c06f4'	System	09 Aug 2020 23:35:23
User entered 'No (N)'	System	09 Aug 2020 23:35:23

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:35:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0597d47d-7f7b-4353-b222-e2a08d4c06f4'	System	09 Aug 2020 23:35:23
User entered 'None (1)'	System	09 Aug 2020 23:35:23

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:35:16', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0597d47d-7f7b-4353-b222-e2a08d4c06f4'	System	09 Aug 2020 23:35:23
User entered '09 Aug 2020 19:35'	System	09 Aug 2020 23:35:23

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 7'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:52', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ea10c997-db50-4eee-9501-4bceb9991135'	System	11 Aug 2020 01:00:22
User entered 'None (1)'	System	11 Aug 2020 01:00:22

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ea10c997-db50-4eee-9501-4bceb9991135'	System	11 Aug 2020 01:00:22
User entered 'No (N)'	System	11 Aug 2020 01:00:22

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T20:59:59', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ea10c997-db50-4eee-9501-4bceb9991135'	System	11 Aug 2020 01:00:22
User entered 'No (N)'	System	11 Aug 2020 01:00:22

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:05', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ea10c997-db50-4eee-9501-4bceb9991135'	System	11 Aug 2020 01:00:22
User entered 'None (1)'	System	11 Aug 2020 01:00:22

US3402212

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ea10c997-db50-4eee-9501-4bceb9991135'	System	11 Aug 2020 01:00:22
User entered '10 Aug 2020 21:00'	System	11 Aug 2020 01:00:22

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:38:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:06', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:09', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:13', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:19', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'None (0)'	System	04 Aug 2020 14:39:42

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered 'No (N)'	System	04 Aug 2020 14:39:42



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-04T10:39:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '0b599ea0-e4c0-412c-8b63-988df8e8769e'	System	04 Aug 2020 14:39:42
User entered '04 Aug 2020 10:39'	System	04 Aug 2020 14:39:42

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 10:25'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 12:55'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Aug 2020 13:50'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 2'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 14:11:58



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 3'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:17', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:35', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:42', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No interference with activity (1)'	System	07 Aug 2020 01:04:07



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:03:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered 'No (N)'	System	07 Aug 2020 01:04:07

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-06T21:04:03', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '4586e00b-2a4a-406f-940e-55e0dd9b36e9'	System	07 Aug 2020 01:04:07
User entered '06 Aug 2020 21:04'	System	07 Aug 2020 01:04:07

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 4'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:26:50', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:28:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:27:12', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'No interference with activity (1)'	System	08 Aug 2020 00:28:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:27:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'None (0)'	System	08 Aug 2020 00:28:20



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:27:50', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'None (0)'	System	08 Aug 2020 00:28:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:27:53', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'None (0)'	System	08 Aug 2020 00:28:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:27:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'None (0)'	System	08 Aug 2020 00:28:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:28:03', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered 'No (N)'	System	08 Aug 2020 00:28:20

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-07T20:28:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '14ada17a-3c55-40e4-9ddd-32c5c88c1398'	System	08 Aug 2020 00:28:20
User entered '07 Aug 2020 20:28'	System	08 Aug 2020 00:28:20

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 5'	System	04 Aug 2020 14:11:58



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:32', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:35', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:43', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:47', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:13:50', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'None (0)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:14:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered 'No (N)'	System	09 Aug 2020 02:14:20

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-08T22:14:13', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '291f56e7-51f6-4a4d-b897-7ea4b5d38314'	System	09 Aug 2020 02:14:20
User entered '08 Aug 2020 22:14'	System	09 Aug 2020 02:14:20



**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 6'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'None (0)'	System	09 Aug 2020 23:34:52

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:32', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered 'No (N)'	System	09 Aug 2020 23:34:52

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-09T19:34:45', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b9168b95-b8a6-48f9-a105-52c8a6135087'	System	09 Aug 2020 23:34:52
User entered '09 Aug 2020 19:34'	System	09 Aug 2020 23:34:52

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 7'	System	04 Aug 2020 14:11:58

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05



US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:30', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:41', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'None (0)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:50', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered 'No (N)'	System	11 Aug 2020 01:01:05

US3402212

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (57fbb4cf46f1dc10)', Time: '2020-08-10T21:00:54', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3c9c6550-e663-4daa-89dd-a269dc60b4e3'	System	11 Aug 2020 01:01:05
User entered '10 Aug 2020 21:00'	System	11 Aug 2020 01:01:05

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 14:11:58

**US3402212**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 14:11:58



**US3402212**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	19 Aug 2020 12:22:43
	Traci Hull (b) (4)	
	(b) (4)	

US3402212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Feb 2021 17:12:36
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 12:23:15
Query 'Safety Call Day 8 'Date of Contact or Contact System Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).		19 Aug 2020 12:23:15
User entered '11 Aug 2020' reason for change: Data Entry Error	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:15
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	19 Aug 2020 12:22:43
User entered '4 Aug 2020'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:22:43

**US3402212**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	19 Aug 2020 12:22:43

**US3402212**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Traci Hull (b) (4)	19 Aug 2020 12:22:43

US3402212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	19 Aug 2020 12:23:24
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	19 Aug 2020 12:23:24

**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered 'Yes (Y)'	(b) (4)	19 Aug 2020 12:23:40
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered '18 Aug 2020'	Traci Hull (b) (4)	19 Aug 2020 12:23:40



**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	19 Aug 2020 12:23:40

**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered empty.	Traci Hull (b) (4)	19 Aug 2020 12:23:40

**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered 'Yes (Y)'	Traci Hull (b) (4)	19 Aug 2020 12:23:48

**US3402212**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User entered 'I'	System	19 Aug 2020 12:23:48

**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	25 Aug 2020 20:31:25

**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '25 Aug 2020'	Traci Hull (b) (4)	25 Aug 2020 20:31:25

**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	25 Aug 2020 20:31:25

**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Traci Hull (b) (4)	25 Aug 2020 20:31:25



**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:04
User entered 'Yes (Y)'	Traci Hull (b) (4)	25 Aug 2020 20:31:31

**US3402212**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User entered 'I'	System	25 Aug 2020 20:31:31

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:01

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:01

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:01

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'VISIT2'	System	04 Sep 2020 12:18:01

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Pre-Dose (PREDOSE)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	04 Sep 2020 13:25:06



US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	(b) (4) Traci Hull (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '07:27'	Traci Hull (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Sep 2020 07:27'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '98.2' F	Traci Hull (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '62'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'bpm'	System	04 Sep 2020 13:25:06



US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'breaths/min'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '113'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '64'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Post-Dose (POSTDOSE)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06



US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	(b) (4) Traci Hull (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '08:37'	Traci Hull (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Sep 2020 08:37'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '98.1' F	(b) (4)	
	Traci Hull (b) (4)	04 Sep 2020 13:25:06
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '62'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'bpm'	System	04 Sep 2020 13:25:06



US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '14'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'breaths/min'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '123'	(b) (4)	
	Traci Hull (b) (4)	04 Sep 2020 13:25:06
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '68'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	04 Sep 2020 13:25:06

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	04 Sep 2020 13:25:34
	(b) (4)	

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	(b) (4) Traci Hull (b) (4)	04 Sep 2020 13:25:34



US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '08:04'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Sep 2020 08:04'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33



US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'ONCE'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:22:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	04 Sep 2020 13:25:55

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	Traci Hull (b) (4)	04 Sep 2020 13:25:55

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '07:45'	(b) (4)	
	Traci Hull (b) (4)	04 Sep 2020 13:25:55
	(b) (4)	

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Sep 2020 07:45'	System	04 Sep 2020 13:25:55

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 17:22:36**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '4 Sep 2020'	Traci Hull (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:12



**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '07:42'	Traci Hull (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '4 Sep 2020 07:42'	System	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:12

**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered empty.	System	04 Sep 2020 13:26:12

US3402212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	04 Sep 2020 13:26:19



**US3402212**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	04 Sep 2020 13:26:19

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 08:24'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 10:54'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bc5b8e01-d7e9-405d-9c18-eaf29d332d02'	System	05 Sep 2020 00:14:41
User entered 'Yes (Y)'	System	05 Sep 2020 00:14:41

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bc5b8e01-d7e9-405d-9c18-eaf29d332d02'	System	05 Sep 2020 00:14:41
User entered '97.0'	System	05 Sep 2020 00:14:41

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:30', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bc5b8e01-d7e9-405d-9c18-eaf29d332d02'	System	05 Sep 2020 00:14:41
User entered 'No (N)'	System	05 Sep 2020 00:14:41

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bc5b8e01-d7e9-405d-9c18-eaf29d332d02'	System	05 Sep 2020 00:14:41
User entered '04 Sep 2020 20:14'	System	05 Sep 2020 00:14:41

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 11:49'	System	04 Sep 2020 12:18:33



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 2'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:12:47', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d4d41b-3406-46af-a84e-4c0768cbb935'	System	06 Sep 2020 00:13:10
User entered 'Yes (Y)'	System	06 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:12:58', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d4d41b-3406-46af-a84e-4c0768cbb935' User entered '98.2'	System	06 Sep 2020 00:13:10
	System	06 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:02', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d4d41b-3406-46af-a84e-4c0768cbb935'	System	06 Sep 2020 00:13:10
User entered 'No (N)'	System	06 Sep 2020 00:13:10

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:07', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d4d41b-3406-46af-a84e-4c0768cbb935'	System	06 Sep 2020 00:13:10
User entered '05 Sep 2020 20:13'	System	06 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 12:18:33



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 3'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:57:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '163920fd-40e2-4366-ac19-fdec6925156'	System	06 Sep 2020 23:58:21
User entered 'Yes (Y)'	System	06 Sep 2020 23:58:21

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '163920fd-40e2-4366-ac19-fdec6925156' User entered '98.0'	System	06 Sep 2020 23:58:21
	System	06 Sep 2020 23:58:21

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:10', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '163920fd-40e2-4366-ac19-fdec6925156'	System	06 Sep 2020 23:58:21
User entered 'No (N)'	System	06 Sep 2020 23:58:21

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:19', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '163920fd-40e2-4366-ac19-fdec6925156'	System	06 Sep 2020 23:58:21
User entered '06 Sep 2020 19:58'	System	06 Sep 2020 23:58:21

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 4'	System	04 Sep 2020 12:18:33



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:11:58', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '7e458370-39a8-40d8-b3f3-64f5e4a85f1c' User entered 'Yes (Y)'	System	08 Sep 2020 00:12:18
	System	08 Sep 2020 00:12:18

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '7e458370-39a8-40d8-b3f3-64f5e4a85f1c' User entered '98.7'	System	08 Sep 2020 00:12:18
	System	08 Sep 2020 00:12:18

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:12', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '7e458370-39a8-40d8-b3f3-64f5e4a85f1c'	System	08 Sep 2020 00:12:18
User entered 'No (N)'	System	08 Sep 2020 00:12:18

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:16', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '7e458370-39a8-40d8-b3f3-64f5e4a85f1c' User entered '07 Sep 2020 20:12'	System	08 Sep 2020 00:12:18
	System	08 Sep 2020 00:12:18

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 5'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:18:29', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '9d20d6a0-0323-401d-b5ea-a7ce68897cdc' User entered 'Yes (Y)'	System	09 Sep 2020 00:18:51
	System	09 Sep 2020 00:18:51



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:18:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '9d20d6a0-0323-401d-b5ea-a7ce68897cdc' User entered '98.6'	System	09 Sep 2020 00:18:51
	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:18:44', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '9d20d6a0-0323-401d-b5ea-a7ce68897cdc' User entered 'No (N)'	System	09 Sep 2020 00:18:51
	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:22:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:18:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '9d20d6a0-0323-401d-b5ea-a7ce68897cdc' User entered '08 Sep 2020 20:18'	System	09 Sep 2020 00:18:51
	System	09 Sep 2020 00:18:51

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 6'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:19:57', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3a377991-d68d-47ba-a887-7f8b09d9c44a' User entered 'Yes (Y)'	System	10 Sep 2020 00:20:17
	System	10 Sep 2020 00:20:17

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3a377991-d68d-47ba-a887-7f8b09d9c44a' User entered '98.1'	System	10 Sep 2020 00:20:17
	System	10 Sep 2020 00:20:17



US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3a377991-d68d-47ba-a887-7f8b09d9c44a'	System	10 Sep 2020 00:20:17
User entered 'No (N)'	System	10 Sep 2020 00:20:17

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3a377991-d68d-47ba-a887-7f8b09d9c44a' User entered '09 Sep 2020 20:20'	System	10 Sep 2020 00:20:17
	System	10 Sep 2020 00:20:17

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 7'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:21:45', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '8850737b-2bfa-4bb4-bc7c-dfd9e647e376' User entered 'Yes (Y)'	System	11 Sep 2020 00:22:04
	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:21:51', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '8850737b-2bfa-4bb4-bc7c-dfd9e647e376' User entered '98.6'	System	11 Sep 2020 00:22:04
	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:21:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '8850737b-2bfa-4bb4-bc7c-dfd9e647e376'	System	11 Sep 2020 00:22:04
User entered 'No (N)'	System	11 Sep 2020 00:22:04



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:21:59', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '8850737b-2bfa-4bb4-bc7c-dfd9e647e376' User entered '10 Sep 2020 20:21'	System	11 Sep 2020 00:22:04
	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 08:24'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 10:54'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:50', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e8594b29-71b2-4009-ba3b-2e204dee56a9' User entered 'None (1)'	System	05 Sep 2020 00:15:20
	System	05 Sep 2020 00:15:20

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:14:54', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e8594b29-71b2-4009-ba3b-2e204dee56a9' User entered 'No (N)'	System	05 Sep 2020 00:15:20
	System	05 Sep 2020 00:15:20



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:01', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e8594b29-71b2-4009-ba3b-2e204dee56a9' User entered 'No (N)'	System	05 Sep 2020 00:15:20
	System	05 Sep 2020 00:15:20

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e8594b29-71b2-4009-ba3b-2e204dee56a9'	System	05 Sep 2020 00:15:20
User entered 'None (1)'	System	05 Sep 2020 00:15:20

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e8594b29-71b2-4009-ba3b-2e204dee56a9' User entered '04 Sep 2020 20:15'	System	05 Sep 2020 00:15:20
	System	05 Sep 2020 00:15:20

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 11:49'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 2'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '118a06ca-dbd3-47dc-8335-dc96ccfee335'	System	06 Sep 2020 00:13:37
User entered 'None (1)'	System	06 Sep 2020 00:13:37

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:19', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '118a06ca-dbd3-47dc-8335-dc96ccfee335'	System	06 Sep 2020 00:13:37
User entered 'No (N)'	System	06 Sep 2020 00:13:37



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '118a06ca-dbd3-47dc-8335-dc96ccfee335'	System	06 Sep 2020 00:13:37
User entered 'No (N)'	System	06 Sep 2020 00:13:37

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '118a06ca-dbd3-47dc-8335-dc96ccfee335'	System	06 Sep 2020 00:13:37
User entered 'None (1)'	System	06 Sep 2020 00:13:37

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '118a06ca-dbd3-47dc-8335-dc96ccfee335' User entered '05 Sep 2020 20:13'	System	06 Sep 2020 00:13:37
	System	06 Sep 2020 00:13:37

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:22:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 3'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'daa4abe1-06b6-40bd-8a81-ada7cab95406' User entered 'None (1)'	System	06 Sep 2020 23:58:53
	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'daa4abe1-06b6-40bd-8a81-ada7cab95406' User entered 'No (N)'	System	06 Sep 2020 23:58:53
	System	06 Sep 2020 23:58:53



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:35', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'daa4abe1-06b6-40bd-8a81-ada7cab95406' User entered 'No (N)'	System	06 Sep 2020 23:58:53
	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:42', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'daa4abe1-06b6-40bd-8a81-ada7cab95406' User entered 'None (1)'	System	06 Sep 2020 23:58:53
	System	06 Sep 2020 23:58:53

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'daa4abe1-06b6-40bd-8a81-ada7cab95406' User entered '06 Sep 2020 19:58'	System	06 Sep 2020 23:58:53
	System	06 Sep 2020 23:58:53

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 4'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3ad3d8cd-3bf9-49f0-854a-1540f848acf7'	System	08 Sep 2020 00:12:40
User entered 'None (1)'	System	08 Sep 2020 00:12:40

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3ad3d8cd-3bf9-49f0-854a-1540f848acf7' User entered 'No (N)'	System	08 Sep 2020 00:12:40
	System	08 Sep 2020 00:12:40



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:28', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3ad3d8cd-3bf9-49f0-854a-1540f848acf7' User entered 'No (N)'	System	08 Sep 2020 00:12:40
	System	08 Sep 2020 00:12:40

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3ad3d8cd-3bf9-49f0-854a-1540f848acf7' User entered 'None (1)'	System	08 Sep 2020 00:12:40
	System	08 Sep 2020 00:12:40

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3ad3d8cd-3bf9-49f0-854a-1540f848acf7' User entered '07 Sep 2020 20:12'	System	08 Sep 2020 00:12:40
	System	08 Sep 2020 00:12:40

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 5'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:18:59', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f4482984-c264-48e2-a6c5-52b50bd2f86e' User entered 'None (1)'	System	09 Sep 2020 00:19:15
	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:02', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f4482984-c264-48e2-a6c5-52b50bd2f86e' User entered 'No (N)'	System	09 Sep 2020 00:19:15
	System	09 Sep 2020 00:19:15



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:06', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f4482984-c264-48e2-a6c5-52b50bd2f86e' User entered 'No (N)'	System	09 Sep 2020 00:19:15
	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:10', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f4482984-c264-48e2-a6c5-52b50bd2f86e' User entered 'None (1)'	System	09 Sep 2020 00:19:15
	System	09 Sep 2020 00:19:15

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:13', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'f4482984-c264-48e2-a6c5-52b50bd2f86e' User entered '08 Sep 2020 20:19'	System	09 Sep 2020 00:19:15
	System	09 Sep 2020 00:19:15

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 6'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:20', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ac59da75-424b-4b1e-be2f-22a4e9a10eda' User entered 'None (1)'	System	10 Sep 2020 00:20:41
	System	10 Sep 2020 00:20:41

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ac59da75-424b-4b1e-be2f-22a4e9a10eda' User entered 'No (N)'	System	10 Sep 2020 00:20:41
	System	10 Sep 2020 00:20:41



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:29', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ac59da75-424b-4b1e-be2f-22a4e9a10eda' User entered 'No (N)'	System	10 Sep 2020 00:20:41
	System	10 Sep 2020 00:20:41

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:36', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ac59da75-424b-4b1e-be2f-22a4e9a10eda' User entered 'None (1)'	System	10 Sep 2020 00:20:41
	System	10 Sep 2020 00:20:41

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ac59da75-424b-4b1e-be2f-22a4e9a10eda' User entered '09 Sep 2020 20:20'	System	10 Sep 2020 00:20:41
	System	10 Sep 2020 00:20:41

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 7'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:05', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '46d657b0-7d96-49a6-bb55-4d20a5ae1aa5'	System	11 Sep 2020 00:22:23
User entered 'None (1)'	System	11 Sep 2020 00:22:23

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:10', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '46d657b0-7d96-49a6-bb55-4d20a5ae1aa5' User entered 'No (N)'	System	11 Sep 2020 00:22:23
	System	11 Sep 2020 00:22:23



US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:13', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '46d657b0-7d96-49a6-bb55-4d20a5ae1aa5' User entered 'No (N)'	System	11 Sep 2020 00:22:23
	System	11 Sep 2020 00:22:23

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:16', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '46d657b0-7d96-49a6-bb55-4d20a5ae1aa5'	System	11 Sep 2020 00:22:23
User entered 'None (1)'	System	11 Sep 2020 00:22:23

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:20', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '46d657b0-7d96-49a6-bb55-4d20a5ae1aa5' User entered '10 Sep 2020 20:22'	System	11 Sep 2020 00:22:23
	System	11 Sep 2020 00:22:23

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:22:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 08:24'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 10:54'	System	04 Sep 2020 12:18:33



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:30', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:52', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:15:54', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'None (0)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:16:07', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6' User entered 'No (N)'	System	05 Sep 2020 00:16:13
	System	05 Sep 2020 00:16:13



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-04T20:16:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '5962d506-3138-443c-86f7-d61302e686b6'	System	05 Sep 2020 00:16:13
User entered '04 Sep 2020 20:16'	System	05 Sep 2020 00:16:13

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '04 Sep 2020 11:49'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 2'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:38', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:41', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:44', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:49', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:53', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:13:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'None (0)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:14:02', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered 'No (N)'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-05T20:14:06', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '23aae9c6-73c3-4e77-a500-87f6759441cf' User entered '05 Sep 2020 20:14'	System	06 Sep 2020 00:14:08
	System	06 Sep 2020 00:14:08

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 3'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:54', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:58:58', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:01', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:05', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'None (0)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered 'No (N)'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-06T19:59:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '54db4461-5dff-4e39-8e39-d0feb631988a' User entered '06 Sep 2020 19:59'	System	06 Sep 2020 23:59:30
	System	06 Sep 2020 23:59:30

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 12:18:33



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 4'	System	04 Sep 2020 12:18:33

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:40', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:43', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:46', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:49', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:53', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:12:55', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'None (0)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:13:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered 'No (N)'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-07T20:13:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b424cdfd-02ec-4fb8-b55a-df7ea7b47741' User entered '07 Sep 2020 20:13'	System	08 Sep 2020 00:13:10
	System	08 Sep 2020 00:13:10

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 5'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:21', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:28', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'None (0)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:41', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered 'No (N)'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-08T20:19:45', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '3beeb434-4f28-47e7-8fcd-db0e47c2031e' User entered '08 Sep 2020 20:19'	System	09 Sep 2020 00:19:46
	System	09 Sep 2020 00:19:46

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 6'	System	04 Sep 2020 12:18:33



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:47', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:51', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:55', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:20:59', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:21:01', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:21:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'None (0)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:21:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered 'No (N)'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-09T20:21:17', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '19964826-b435-46d9-aa91-4a32d24f92e7' User entered '09 Sep 2020 20:21'	System	10 Sep 2020 00:21:23
	System	10 Sep 2020 00:21:23



**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Sep 2020 12:18:33
User entered 'Day 7'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:25', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered 'None (0)'	System	11 Sep 2020 00:22:49

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered 'None (0)'	System	11 Sep 2020 00:22:49

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:30', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3' User entered 'None (0)'	System	11 Sep 2020 00:22:49
	System	11 Sep 2020 00:22:49

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:33', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3' User entered 'None (0)'	System	11 Sep 2020 00:22:49
	System	11 Sep 2020 00:22:49

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:36', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered 'None (0)'	System	11 Sep 2020 00:22:49



US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered 'None (0)'	System	11 Sep 2020 00:22:49

US3402212

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:22:36

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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:42', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered 'No (N)'	System	11 Sep 2020 00:22:49

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-09-10T20:22:46', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2c38dfd7-3d54-42af-9f99-dc4b83aae7d3'	System	11 Sep 2020 00:22:49
User entered '10 Sep 2020 20:22'	System	11 Sep 2020 00:22:49

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:22:36**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 12:18:33

**US3402212**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	14 Sep 2020 11:32:56
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '11 Sep 2020'	Traci Hull (b) (4)	14 Sep 2020 11:32:56

**US3402212**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	14 Sep 2020 11:32:56



**US3402212**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Traci Hull (b) (4)	14 Sep 2020 11:32:56

US3402212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	14 Sep 2020 11:33:00

**US3402212**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:07
User entered 'I'	System	14 Sep 2020 11:33:00

**US3402212**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 16:57:50

**US3402212**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '18 Sep 2020'	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 16:57:50

**US3402212**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4)	18 Sep 2020 16:57:50

**US3402212**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 16:57:50

US3402212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	18 Sep 2020 16:57:54



**US3402212**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	18 Sep 2020 16:57:54

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	(b) (4)	
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	13 Oct 2020 13:40:44
User entered 'Yes (Y)'	System	13 Oct 2020 13:40:21
	Traci Hull (b) (4)	13 Oct 2020 13:40:21
	(b) (4)	

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:22:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	13 Oct 2020 13:41:11
answered by data change (Site from System).		
User entered '25 Sep 2020' reason for change: Per Query Resolution	System	13 Oct 2020 13:41:11
User opened query 'Safety Call Day 50 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	Traci Hull (b) (4)	13 Oct 2020 13:41:11
User entered '29 Sep 2020' reason for change: Per Query Resolution	(b) (4)	
User entered empty.	System	13 Oct 2020 13:40:44
	Traci Hull (b) (4)	13 Oct 2020 13:40:44
	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:40:21
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Contact Not Made (CONTACT NOT MADE)'	Traci Hull (b) (4)	13 Oct 2020 13:40:21

**US3402212**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'LEFT 3 VOICE MAIL MESSAGES WITH NO CALL BACK'	Traci Hull (b) (4)	13 Oct 2020 13:40:21

**US3402212**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	13 Oct 2020 13:41:15

**US3402212**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	13 Oct 2020 13:41:15

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:41:29
	(b) (4)	



US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User closed query 'Per CDM: Per previous query, Visit 3 date (13Oct2020) is 39 days after Visit 2 date (04Sep2020) which is outside of the window allowance. Please review dates and if correct provide an explanation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Oct 2020 10:24:08
Query 'Per CDM: Per previous query, Visit 3 date (13Oct2020) is 39 days after Visit 2 date (04Sep2020) which is outside of the window allowance. Please review dates and if correct provide an explanation.' answered with 'THE DATE IS CORRECT, PATIENT WAS UNABLE TO COME IN ON TIME' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Oct 2020 16:39:11
User opened query 'Per CDM: Per previous query, Visit 3 date (13Oct2020) is 39 days after Visit 2 date (04Sep2020) which is outside of the window allowance. Please review dates and if correct provide an explanation.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:24:32
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	19 Oct 2020 13:22:39
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'CORRECT AS IS. 34 DAYS TODAY.' (Site from System).	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:43:44
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	13 Oct 2020 13:41:29
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:41:29

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Clinic (Clinic)'	Traci Hull (b) (4)	13 Oct 2020 13:41:29

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'VISIT3'	System	13 Oct 2020 13:41:29

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '13 Oct 2020'	Traci Hull (b) (4)	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:12'	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:44:44
	(b) (4)	

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '13 Oct 2020 09:12'	System	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '97.5' F	Traci Hull (b) (4)	13 Oct 2020 13:44:44



US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Oral (Oral)'	(b) (4) Traci Hull (b) (4)	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Traci Hull (b) (4)	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '71'	Traci Hull (b) (4)	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'bpm'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '14'	Traci Hull (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'breaths/min'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '123'	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:44:44
	(b) (4)	

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	13 Oct 2020 13:44:44



US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '64'	Traci Hull (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'mmHg'	System	13 Oct 2020 13:44:44

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:44:52
	(b) (4)	

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered empty.	Traci Hull (b) (4)	13 Oct 2020 13:44:52

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	13 Oct 2020 13:45:04

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '13 Oct 2020'	(b) (4)	
	Traci Hull (b) (4)	13 Oct 2020 13:45:04
	(b) (4)	



**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered '09:15'	Traci Hull (b) (4)	13 Oct 2020 13:45:04

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered '13 Oct 2020 09:15'	System	13 Oct 2020 13:45:04

US3402212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:22:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	15 Feb 2021 17:12:36
User entered 'Yes (Y)'	Traci Hull (b) (4)	13 Oct 2020 13:45:09

**US3402212**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	13 Oct 2020 13:45:09

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 64'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 14:11:58



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 71'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-10-12T16:46:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a2174240-edd3-43db-9578-06695e9a66cd' User entered 'No (N)'	System	12 Oct 2020 20:46:46
	System	12 Oct 2020 20:46:46

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-10-12T16:46:29', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a2174240-edd3-43db-9578-06695e9a66cd' User entered 'No (N)'	System	12 Oct 2020 20:46:46

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-10-12T16:46:42', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a2174240-edd3-43db-9578-06695e9a66cd' User entered '12 Oct 2020 16:46:42'	System	12 Oct 2020 20:46:46
	System	12 Oct 2020 20:46:46

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 78'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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**Generated On: 09 Jun 2021 17:22:36**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Audit	User	Time (GMT)
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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 92'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:22:36

Have you been exposed to someone with 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 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

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**Generated On: 09 Jun 2021 17:22:36**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:19:28
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 99'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-09T21:29:26', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'd6e1ca86-bf56-4271-8ad0-5300c4ec0aae'	System	10 Nov 2020 02:29:44
User entered 'No (N)'	System	10 Nov 2020 02:29:44



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-09T21:29:31', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'd6e1ca86-bf56-4271-8ad0-5300c4ec0aae'	System	10 Nov 2020 02:29:44
User entered 'No (N)'	System	10 Nov 2020 02:29:44

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-09T21:29:41', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'd6e1ca86-bf56-4271-8ad0-5300c4ec0aae' User entered '09 Nov 2020 21:29:41'	System	10 Nov 2020 02:29:44
	System	10 Nov 2020 02:29:44

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered 'Day 106'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-15T08:29:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'abe23509-0ad0-4188-9961-177c88b898a1'	System	15 Nov 2020 13:30:10
User entered 'No (N)'	System	15 Nov 2020 13:30:10

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-15T08:29:56', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'abe23509-0ad0-4188-9961-177c88b898a1'	System	15 Nov 2020 13:30:10
User entered 'No (N)'	System	15 Nov 2020 13:30:10

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-15T08:30:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'abe23509-0ad0-4188-9961-177c88b898a1' User entered '15 Nov 2020 08:30:08'	System	15 Nov 2020 13:30:10
	System	15 Nov 2020 13:30:10



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 04:07:44
Data entry locked.	System	04 Aug 2020 14:11:58
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 14:11:58

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-22T09:40:15', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'be342f71-583b-4d14-bf44-a04b3369fd1d' User entered 'No (N)'	System	22 Nov 2020 14:40:30
	System	22 Nov 2020 14:40:30

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-22T09:40:21', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'be342f71-583b-4d14-bf44-a04b3369fd1d' User entered 'No (N)'	System	22 Nov 2020 14:40:30

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-22T09:40:28', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'be342f71-583b-4d14-bf44-a04b3369fd1d' User entered '22 Nov 2020 09:40:28'	System	22 Nov 2020 14:40:30
	System	22 Nov 2020 14:40:30

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-29T07:01:17', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d57a3c-4cd9-43e2-a90d-4f841ddeab91' User entered 'No (N)'	System	29 Nov 2020 12:01:36
	System	29 Nov 2020 12:01:36

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-29T07:01:21', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d57a3c-4cd9-43e2-a90d-4f841ddeab91'	System	29 Nov 2020 12:01:36
User entered 'No (N)'	System	29 Nov 2020 12:01:36

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-11-29T07:01:32', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '97d57a3c-4cd9-43e2-a90d-4f841ddeab91' User entered '29 Nov 2020 07:01:32'	System	29 Nov 2020 12:01:36
	System	29 Nov 2020 12:01:36

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-06T09:56:39', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b6515ebd-fb13-4913-8b45-c119940ed233'	System	06 Dec 2020 14:56:49
User entered 'No (N)'	System	06 Dec 2020 14:56:49



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-06T09:56:42', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b6515ebd-fb13-4913-8b45-c119940ed233'	System	06 Dec 2020 14:56:49
User entered 'No (N)'	System	06 Dec 2020 14:56:49

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-06T09:56:47', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b6515ebd-fb13-4913-8b45-c119940ed233' User entered '06 Dec 2020 09:56:47'	System	06 Dec 2020 14:56:49
	System	06 Dec 2020 14:56:49

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-13T07:24:55', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67e15007-0d16-48a3-a062-193220095602'	System	13 Dec 2020 12:25:08
User entered 'No (N)'	System	13 Dec 2020 12:25:08

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-13T07:24:59', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67e15007-0d16-48a3-a062-193220095602'	System	13 Dec 2020 12:25:08
User entered 'No (N)'	System	13 Dec 2020 12:25:08

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-13T07:25:03', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67e15007-0d16-48a3-a062-193220095602'	System	13 Dec 2020 12:25:08
User entered '13 Dec 2020 07:25:03'	System	13 Dec 2020 12:25:08



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-20T09:57:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'aa65a126-81a0-45cb-9cbb-e5b6919b46d5'	System	20 Dec 2020 14:57:20
User entered 'No (N)'	System	20 Dec 2020 14:57:20

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-20T09:57:11', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'aa65a126-81a0-45cb-9cbb-e5b6919b46d5'	System	20 Dec 2020 14:57:20
User entered 'No (N)'	System	20 Dec 2020 14:57:20

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-20T09:57:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'aa65a126-81a0-45cb-9cbb-e5b6919b46d5' User entered '20 Dec 2020 09:57:18'	System	20 Dec 2020 14:57:20
	System	20 Dec 2020 14:57:20

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-27T16:59:14', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '61ef328d-9eb4-436e-a2ee-972a5d0a1ddd' User entered 'No (N)'	System	27 Dec 2020 21:59:24
	System	27 Dec 2020 21:59:24

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-27T16:59:17', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '61ef328d-9eb4-436e-a2ee-972a5d0a1ddd' User entered 'No (N)'	System	27 Dec 2020 21:59:24

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2020-12-27T16:59:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '61ef328d-9eb4-436e-a2ee-972a5d0a1ddd' User entered '27 Dec 2020 16:59:22'	System	27 Dec 2020 21:59:24
	System	27 Dec 2020 21:59:24

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-03T08:48:51', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '038d7281-3965-4d1d-a995-113ca969f004'	System	03 Jan 2021 13:49:11
User entered 'No (N)'	System	03 Jan 2021 13:49:11



**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-03T08:48:55', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '038d7281-3965-4d1d-a995-113ca969f004'	System	03 Jan 2021 13:49:11
User entered 'No (N)'	System	03 Jan 2021 13:49:11

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-03T08:49:08', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '038d7281-3965-4d1d-a995-113ca969f004'	System	03 Jan 2021 13:49:11
User entered '03 Jan 2021 08:49:08'	System	03 Jan 2021 13:49:11

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:19:28

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-10T09:58:45', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bb3ddc1f-bdbb-4b23-8307-94870c8bc5f5'	System	10 Jan 2021 14:58:59
User entered 'No (N)'	System	10 Jan 2021 14:58:59

**US3402212**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-10T09:58:18', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bb3ddc1f-bdbb-4b23-8307-94870c8bc5f5'	System	10 Jan 2021 14:58:59
User entered 'No (N)'	System	10 Jan 2021 14:58:59

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-10T09:58:57', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'bb3ddc1f-bdbb-4b23-8307-94870c8bc5f5' User entered '10 Jan 2021 09:58:57'	System	10 Jan 2021 14:58:59



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-17T07:36:01', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '27d17bfb-54c9-49c6-b524-35e6c4bb3b02' User entered 'No (N)'	System	17 Jan 2021 12:36:52
	System	17 Jan 2021 12:36:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-17T07:36:16', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '27d17bfb-54c9-49c6-b524-35e6c4bb3b02'	System	17 Jan 2021 12:36:52
User entered 'No (N)'	System	17 Jan 2021 12:36:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-17T07:36:49', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '27d17bfb-54c9-49c6-b524-35e6c4bb3b02' User entered '17 Jan 2021 07:36:49'	System	17 Jan 2021 12:36:52
	System	17 Jan 2021 12:36:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-24T08:37:15', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'df945ac7-8210-495e-8a8b-9a45cc25e963' User entered 'No (N)'	System	24 Jan 2021 13:37:37
	System	24 Jan 2021 13:37:37

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-24T08:37:20', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'df945ac7-8210-495e-8a8b-9a45cc25e963'	System	24 Jan 2021 13:37:37
User entered 'No (N)'	System	24 Jan 2021 13:37:37

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-01-24T08:37:33', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'df945ac7-8210-495e-8a8b-9a45cc25e963' User entered '24 Jan 2021 08:37:33'	System	24 Jan 2021 13:37:37
	System	24 Jan 2021 13:37:37

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-01T08:00:23', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e6f4a37f-0bd1-4782-b687-7b32348cce98'	System	01 Feb 2021 13:00:39
User entered 'No (N)'	System	01 Feb 2021 13:00:39



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-01T08:00:27', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e6f4a37f-0bd1-4782-b687-7b32348cce98'	System	01 Feb 2021 13:00:39
User entered 'No (N)'	System	01 Feb 2021 13:00:39

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-01T08:00:33', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'e6f4a37f-0bd1-4782-b687-7b32348cce98' User entered '01 Feb 2021 08:00:33'	System	01 Feb 2021 13:00:39
	System	01 Feb 2021 13:00:39

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:41:37', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068'	System	07 Feb 2021 18:43:23
User entered 'Yes (Y)'	System	07 Feb 2021 18:43:23

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:41:48', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068'	System	07 Feb 2021 18:43:23
User entered 'No (N)'	System	07 Feb 2021 18:43:23

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:42:04', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068' User entered 'No (N)'	System	07 Feb 2021 18:43:23



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:42:24', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068'	System	07 Feb 2021 18:43:23
User entered 'Yes (Y)'	System	07 Feb 2021 18:43:23

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:43:03', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068'	System	07 Feb 2021 18:43:23
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Feb 2021 18:43:23

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-07T13:43:12', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b60fb740-07c1-480a-97f0-148d70383068' User entered '07 Feb 2021 13:43:12'	System	07 Feb 2021 18:43:23
	System	07 Feb 2021 18:43:23

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-14T12:47:29', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67194e19-0a3c-4698-845d-7d7a221e7879' User entered 'No (N)'	System	14 Feb 2021 17:47:44
	System	14 Feb 2021 17:47:44

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-14T12:47:34', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67194e19-0a3c-4698-845d-7d7a221e7879'	System	14 Feb 2021 17:47:44
User entered 'No (N)'	System	14 Feb 2021 17:47:44



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-14T12:47:40', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '67194e19-0a3c-4698-845d-7d7a221e7879' User entered '14 Feb 2021 12:47:40'	System	14 Feb 2021 17:47:44
	System	14 Feb 2021 17:47:44

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-21T14:28:47', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a5b647b0-0dcd-4b10-be4e-2b4653eb8cc4' User entered 'No (N)'	System	21 Feb 2021 19:29:00
	System	21 Feb 2021 19:29:00

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-21T14:28:52', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a5b647b0-0dcd-4b10-be4e-2b4653eb8cc4' User entered 'No (N)'	System	21 Feb 2021 19:29:00

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-21T14:28:57', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a5b647b0-0dcd-4b10-be4e-2b4653eb8cc4' User entered '21 Feb 2021 14:28:57'	System	21 Feb 2021 19:29:00

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-28T13:03:15-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2f12fc39-2b74-40b7-a1b5-5fd1d7620c83'	System	28 Feb 2021 18:07:09
User entered 'No (N)'	System	28 Feb 2021 18:07:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-28T13:03:18-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2f12fc39-2b74-40b7-a1b5-5fd1d7620c83'	System	28 Feb 2021 18:07:09
User entered 'No (N)'	System	28 Feb 2021 18:07:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-28T13:03:22-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '2f12fc39-2b74-40b7-a1b5-5fd1d7620c83' User entered '28 Feb 2021 18:03:22'	System	28 Feb 2021 18:07:09
	System	28 Feb 2021 18:07:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-03-07T18:10:07-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ed4b5ce7-b4e8-426b-a5c5-fdf8bb209815'	System	07 Mar 2021 23:14:12
User entered 'No (N)'	System	07 Mar 2021 23:14:12

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-03-07T18:10:11-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ed4b5ce7-b4e8-426b-a5c5-fdf8bb209815'	System	07 Mar 2021 23:14:12
User entered 'No (N)'	System	07 Mar 2021 23:14:12

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-03-07T18:10:21-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'ed4b5ce7-b4e8-426b-a5c5-fdf8bb209815' User entered '07 Mar 2021 18:10:21'	System	07 Mar 2021 23:14:12
	System	07 Mar 2021 23:14:12

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:25:52-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b' User entered 'Yes (Y)'	System	13 Apr 2021 03:26:52
	System	13 Apr 2021 03:26:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:26:01-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b' User entered 'No (N)'	System	13 Apr 2021 03:26:52
	System	13 Apr 2021 03:26:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:26:08-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b' User entered 'No (N)'	System	13 Apr 2021 03:26:52
	System	13 Apr 2021 03:26:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:26:20-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b'	System	13 Apr 2021 03:26:52
User entered 'Yes (Y)'	System	13 Apr 2021 03:26:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Please 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:26:31-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b'	System	13 Apr 2021 03:26:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Apr 2021 03:26:52

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-12T23:26:37-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'b54b6987-d4ed-4fac-81da-e4abbc77976b' User entered '12 Apr 2021 23:26:37'	System	13 Apr 2021 03:26:52
	System	13 Apr 2021 03:26:52



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-18T09:07:43-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '603666cc-5827-48d4-8e88-cbcbf5762a5d' User entered 'No (N)'	System	18 Apr 2021 13:08:09
	System	18 Apr 2021 13:08:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-18T09:07:48-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '603666cc-5827-48d4-8e88-cbcbf5762a5d' User entered 'No (N)'	System	18 Apr 2021 13:08:09
	System	18 Apr 2021 13:08:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-18T09:08:03-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '603666cc-5827-48d4-8e88-cbcbf5762a5d' User entered '18 Apr 2021 09:08:03'	System	18 Apr 2021 13:08:09
	System	18 Apr 2021 13:08:09

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:01-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157'	System	25 Apr 2021 23:28:43
User entered 'Yes (Y)'	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:05-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157'	System	25 Apr 2021 23:28:43
User entered 'No (N)'	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:11-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157' User entered 'No (N)'	System	25 Apr 2021 23:28:43
	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:21-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157'	System	25 Apr 2021 23:28:43
User entered 'Yes (Y)'	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Please 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:27-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157'	System	25 Apr 2021 23:28:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-04-25T19:28:33-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '469caf20-4825-43e8-9b48-565e53479157'	System	25 Apr 2021 23:28:43
User entered '25 Apr 2021 19:28:33'	System	25 Apr 2021 23:28:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-05-02T22:23:22-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '1a072bef-ec62-47bd-9686-ecc109442a13'	System	03 May 2021 02:23:43
User entered 'No (N)'	System	03 May 2021 02:23:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

Have you been exposed to someone with 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 (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-05-02T22:23:27-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '1a072bef-ec62-47bd-9686-ecc109442a13'	System	03 May 2021 02:23:43
User entered 'No (N)'	System	03 May 2021 02:23:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-05-02T22:23:40-04:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '1a072bef-ec62-47bd-9686-ecc109442a13'	System	03 May 2021 02:23:43
User entered '02 May 2021 22:23:40'	System	03 May 2021 02:23:43

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:19:28



**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:19:28

**US3402212**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:22:36**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:19:28



US3402212

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:22:36

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)	26 Apr 2021 06:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-28T13:04:01-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '052589d3-84fc-451b-8632-a2817707b2e7'	System	28 Feb 2021 18:08:24
User entered 'No (N)'	System	28 Feb 2021 18:08:24

**US3402212**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:36:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CAB39675-3AA4-4CD7-B062-CF6FD368F42F)', Time: '2021-02-28T13:04:16-05:00', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: '052589d3-84fc-451b-8632-a2817707b2e7' User entered '28 Feb 2021 18:04:16'	System	28 Feb 2021 18:08:24
	System	28 Feb 2021 18:08:24

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:38
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Dec 2020 13:56:10

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:38
User entered '28 Oct 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	03 Dec 2020 13:56:10

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:38
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	03 Dec 2020 13:56:10

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:38
User entered empty.	Traci Hull (b) (4)	03 Dec 2020 13:56:10

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User signature succeeded.	Frank Eder (b) (4)	08 Mar 2021 22:20:38
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	01 Dec 2020 19:20:38

**US3402212**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 18:47:14
User entered 'I'	System	01 Dec 2020 19:20:38



**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	Traci Hull (b) (4)	01 Dec 2020 19:20:53

**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '1 Dec 2020'	Traci Hull (b) (4)	01 Dec 2020 19:20:53

**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4)	01 Dec 2020 19:20:53

**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	Traci Hull (b) (4)	01 Dec 2020 19:20:53

**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	01 Dec 2020 19:20:57
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User entered 'I'	System	01 Dec 2020 19:20:57

**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Jan 2021 01:39:11

**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '30 Dec 2020'	Jennifer Molstead (b) (4)	14 Jan 2021 01:39:11



**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Contact Made (CONTACT MADE)'	Jennifer Molstead (b) (4)	14 Jan 2021 01:39:11

**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	Jennifer Molstead (b) (4)	14 Jan 2021 01:39:11

**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	14 Jan 2021 01:39:31

**US3402212**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User entered 'I'	System	14 Jan 2021 01:39:31

**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Feb 2021 18:54:45

**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '29 Jan 2021'	(b) (4) Tammy Kohn (b) (4)	11 Feb 2021 18:54:45

**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4)	11 Feb 2021 18:54:45

**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	11 Feb 2021 18:54:45
	(b) (4)	



**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	11 Feb 2021 18:54:48

**US3402212**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:01:33
User entered 'I'	System	11 Feb 2021 18:54:48

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 21:09:17
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 21:09:17
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[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 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Clinic (Clinic)'	(b) (4)	02 Mar 2021 21:09:17
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered 'VISIT4'	System	02 Mar 2021 21:09:17

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54



**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered empty.	System	31 Mar 2021 17:18:54

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered empty.	System	31 Mar 2021 17:18:54

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54



**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered empty.	System	31 Mar 2021 17:18:54

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered empty.	System	31 Mar 2021 17:18:54

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4) Tammy Kohn (b) (4)	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered empty.	System	31 Mar 2021 17:18:54

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:22:36**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36

US3402212

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:22:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'No (N)'	(b) (4)	02 Mar 2021 21:09:23
	Traci Hull (b) (4)	
	(b) (4)	



**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:22:36**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered empty.	(b) (4)	02 Mar 2021 21:09:23
	Traci Hull (b) (4)	
	(b) (4)	

US3402212

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 21:09:36
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '2 Mar 2021'	(b) (4)	
	Traci Hull (b) (4)	02 Mar 2021 21:09:36
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '09:15'	(b) (4)	02 Mar 2021 21:09:36
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered '2 Mar 2021 09:15'	System	02 Mar 2021 21:09:36

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	02 Mar 2021 21:09:41
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:36:36
User entered 'I'	System	02 Mar 2021 21:09:41

**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	01 Apr 2021 15:16:57
	(b) (4)	



**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
	(b) (4)	
User entered '1 Apr 2021'	Tammy Kohn (b) (4)	01 Apr 2021 15:16:57
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 15:16:57

**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:22:36**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
	(b) (4)	
User entered empty.	Tammy Kohn (b) (4)	01 Apr 2021 15:16:57
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
	(b) (4)	
User entered 'Yes (Y)'	Tammy Kohn (b) (4)	01 Apr 2021 15:17:01
	(b) (4)	

**US3402212**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 15:17:01

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	19 Jan 2021 19:30:39
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '18 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:30:39
	(b) (4)	

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:22:36

[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 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Clinic (Clinic)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:30:39



**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:22:36**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:30:39

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '06 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:31:42
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[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 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '0'	(b) (4) Tammy Kohn (b) (4)	09 Apr 2021 13:17:35
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 11:20:03

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	19 Jan 2021 19:31:42
	Traci Hull (b) (4)	
	(b) (4)	

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
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) (4), (b) (6)	10 Apr 2021 05:58:16
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 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:17:38
User entered 'Amendment 6 or later (Amendment 6 or later)'	Tammy Kohn (b) (4) (b) (4)	09 Apr 2021 13:17:35
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)	08 Apr 2021 15:41:52
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:20:03

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '18 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:31:42
	(b) (4)	

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:22:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:31:42

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:08:33
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4)	19 Jan 2021 19:31:42
	(b) (4)	



**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:08:33
User entered 'mRNA-1273 (mRNA-1273)'	Traci Hull (b) (4)	19 Jan 2021 19:31:42
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'No (N)'	(b) (4)	19 Jan 2021 19:31:42
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User entered empty.	System	19 Jan 2021 19:31:42

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:22:36**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User entered empty.	System	19 Jan 2021 19:31:42

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4)	19 Jan 2021 19:31:56
	Traci Hull (b) (4)	
	(b) (4)	

US3402212

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:22:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Jan 2021 19:32:04
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	19 Jan 2021 19:32:04
User entered '18 Jan 2021' reason for change: New Information	Traci Hull (b) (4)	19 Jan 2021 19:32:04
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	19 Jan 2021 19:31:56
User entered '19 Jan 2021'	System	19 Jan 2021 19:31:56
	Traci Hull (b) (4)	19 Jan 2021 19:31:56
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '14:50'	(b) (4)	19 Jan 2021 19:31:56
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User entered '18 Jan 2021 14:50'	System	19 Jan 2021 19:32:04
User entered '19 Jan 2021 14:50'	System	19 Jan 2021 19:31:56



**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:22:36**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:32:17

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '18 Jan 2021'	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:32:17
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:22:36**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
User entered '14:52'	(b) (4)	19 Jan 2021 19:32:17
	Traci Hull (b) (4)	
	(b) (4)	

**US3402212**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:22:36**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 23:34:38
User entered '18 Jan 2021 14:52'	System	19 Jan 2021 19:32:17

US3402212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:22:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 10:27:19
Query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'UPDATE TO SUBJECTS MEDICATION. ' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 15:22:49
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 187, '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 within this timeframe. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 17:38:49
User signature succeeded.	Frank Eder (b) (4) (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:23:13
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:42:49

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:22
User entered	System	26 Aug 2020 14:04:15
'USA-US059-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	26 Aug 2020 14:04:15

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
User closed query 'Per DM CLR: Please review this worsening AE and please note that there is no baseline MH or prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 10:25:58
Query 'Per DM CLR: Please review this worsening AE and please note that there is no baseline MH or prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' answered with 'OSTEOARTHRITIS OF THE SPINE IS NOTED IN THE MEDICAL HISTORY' (Site from DM).	Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:36:23
User opened query 'Per DM CLR: Please review this worsening AE and please note that there is no baseline MH or prior AE record that would support this worsening condition. Please update to record the baseline condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:19:17
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:01:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:19:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:19:46
Data point term sent to Coder	System	12 Nov 2020 12:21:13
DataPoint Un-verified.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:20:39
Coding entries removed.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:20:39
User entered 'WORSENING Spinal Stenosis' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:20:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query ""Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.  Per DM CLR: SAE Narrative: SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, OF WHICH SHE DID NOT KNOW THE NAME. However, this medication is not recorded on the CM eCRF. Please make sure that medications and procedures are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies." ' (Site from DM). Query ""Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4), (b) (6) Jennifer Molstead (b) (4)	07 Oct 2020 14:59:36 03 Oct 2020 18:45:04
Per DM CLR: SAE Narrative: SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, OF WHICH SHE DID NOT KNOW THE NAME. However, this medication is not recorded on the CM eCRF. Please make sure that medications and procedures are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies." ' answered with 'Still waiting on medical records. Term correct as is' (Site from DM). User opened query ""Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.  Per DM CLR: SAE Narrative: SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, OF WHICH SHE DID NOT KNOW THE NAME. However, this medication is not recorded on the CM eCRF. Please make sure that medications and procedures are recorded in their respective eCRFs. Otherwise, clarify the inconsistencies." ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 07:02:53

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1823 of 2777



US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please consider updating event term to worsening of lower back spasms.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:30:34
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 16:27:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 16:27:51
Data point term sent to Coder	System	14 Sep 2020 01:20:26
Query 'PV Query: Please consider updating event term to worsening of lower back spasms.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	14 Sep 2020 01:20:09
Coding entries removed.	Jennifer Molstead (b) (4)	14 Sep 2020 01:19:55
User entered 'Worsening LOWER BACK SPASMS' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	14 Sep 2020 01:19:55
User opened query 'PV Query: Please consider updating event term to worsening of lower back spasms.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:32:28
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Back muscle spasms - version MedDRA\23.0.	Coder Import (b) (4)	26 Aug 2020 07:06:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	26 Aug 2020 07:06:37
Data point term sent to Coder	System	25 Aug 2020 19:49:42
User entered 'Lower back Spasms'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 10:39:48
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	04 Sep 2020 12:18:33
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 01:19:55
User entered empty; reason for change Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:19:55
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	25 Aug 2020 19:48:55
User entered '06:30'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 01:19:55
User entered '23 Aug 2020 06:30'	System	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55



US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:08:43
DataPoint Un-verified.	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
	(b) (4)	
User entered '29 Sep 2020' reason for change: New Information	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Dec 2020 12:48:34
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'THE GRADE REMAINS A 3 AS THE PATIENT WAS NOT IN GRAVE DANGER. ' (Site from Safety).	Tammy Kohn (b) (4)	02 Dec 2020 17:17:00
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	30 Nov 2020 21:13:48
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Grade 3/Severe (Grade 3/Severe)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'I'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 12:23:06
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Still awaiting medical Records' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	15 Oct 2020 16:52:29
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 15:11:51
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'None (NONE)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User closed query 'Per CDM : Conmed is marked as 'Yes', however in the Conmed eCRF there is no Corresponding Conmed within this timeframe. Kindly update the data as appropriate in both AE and Conmed eCRF else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 08:08:04
Query 'Per CDM : Conmed is marked as 'Yes', however in the Conmed eCRF there is no Corresponding Conmed within this timeframe. Kindly update the data as appropriate in both AE and Conmed eCRF else clarify in query response.' answered with 'awaiting medical records' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	14 Sep 2020 01:20:40
User opened query 'Per CDM : Conmed is marked as 'Yes', however in the Conmed eCRF there is no Corresponding Conmed within this timeframe. Kindly update the data as appropriate in both AE and Conmed eCRF else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 12:00:14
User entered '1'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:17:01
DataPoint Un-verified.	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
User entered '1' reason for change: New Information	(b) (4) Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:45:12
User signature succeeded.	Frank Eder (b) (4)	14 Mar 2021 14:39:45
User closed query ' Per DM CLR: SAE Narrative = SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	24 Dec 2020 03:01:23
User closed query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results if available. If not available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 17:23:45
Query ' Per DM CLR: SAE Narrative = SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:50:21
Query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results if available. If not available, please confirm in your response. ' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:50:15



US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE.WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS GREATER THAN 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, SUBJECT ALSO HAD CHEST X-RAY WHICH WAS NEGATIVE, A MRI OF LUMBAR SPINE THAT SHOWED THE WORSENING OF SPINAL STENOSIS. SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. SUBJECT HAD CONSULT WITH ORTHOPEDIC SURGEON FOR A PLANNED SURGERY. THIS TOOK PLACE 22SEP2020. THE FOLLOWING PROCEDURES WERE PERFORMED, POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. SUBJECT 7 DAYS IN THE HOSPITAL POST OPERATIVELY. SUBJECT ALSO HAD COVID TESTING PRIOR TO SURGERY THAT WAS NEGATIVE. Subject also had another lumbar spine x-ray that confirmed prior lumbar xray that showed worsening of spinal stenosis.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	22 Dec 2020 11:50:07
User opened query ' Per DM CLR: SAE Narrative = SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 04:51:54

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results if available. If not available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 13:55:35
User closed query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 12:47:58
User closed query 'Per DM CLR: Narrative indicates that the subject has a history of Back Spasms. However, there is no corresponding MH record that match the information. Please update to record the MH condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 04:24:50
User closed query 'Per DM CLR: Narrative indicates that the subject had the procedures of POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 04:24:47
Query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	03 Dec 2020 13:33:41
Query 'Per DM CLR: Narrative indicates that the subject has a history of Back Spasms. However, there is no corresponding MH record that match the information. Please update to record the MH condition as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	03 Dec 2020 13:33:34

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that the subject had the procedures of POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.'	Jennifer Molstead (b) (4)	(b) (4) 03 Dec 2020 13:22:39
answered with 'updated' (Site from DM). User opened query 'PV Query: Per the discharge summary, a spinal lumbar x-ray was performed on 22 Sep 2020. Please provide the results.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:13:27
User opened query 'Per DM CLR: Narrative indicates that the subject has a history of Back Spasms. However, there is no corresponding MH record that match the information. Please update to record the MH condition as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:20:52
User opened query 'Per DM CLR: Narrative indicates that the subject had the procedures of POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. However, there are no corresponding Concomitant Procedures record that match the information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 14:20:38

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 16:09:51
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' answered with 'Discharge summary sent' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 23 Nov 2020 20:40:37

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE.WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS GREATER THAN 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, SUBJECT ALSO HAD CHEST X-RAY WHICH WAS NEGATIVE, A MRI OF LUMBAR SPINE THAT SHOWED THE WORSENING OF SPINAL STENOSIS. SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. SUBJECT HAD CONSULT WITH ORTHOPEDIC SURGEON FOR A PLANNED SURGERY. THIS TOOK PLACE 22SEP2020. THE FOLLOWING PROCEDURES WERE PERFORMED, POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. SUBJECT 7 DAYS IN THE HOSPITAL POST OPERATIVELY. SUBJECT ALSO HAD COVID TESTING PRIOR TO SURGERY THAT WAS NEGATIVE.' reason for change: Per Query Resolution	Tammy Kohn (b) (4) (b) (4)	20 Nov 2020 19:20:02
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	20 Nov 2020 18:06:51

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:48
User closed query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:45
User closed query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:41
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:37
User closed query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 13:43:33
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' answered with 'Records will be forwarded.' (Site from Safety).	Jennifer Molstead (b) (4)	12 Nov 2020 19:36:21

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE.WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS GREATER THAN 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, SUBJECT ALSO HAD CHEST X-RAY WHICH WAS NEGATIVE, A MRI OF LUMBAR SPINE THAT SHOWED THE WORSENING OF SPINAL STENOSIS. SUBJECT DID HAVE LAB WORK, BUT RESULTS WERE UNREMARKABLE. SUBJECT HAD CONSULT WITH ORTHOPEDIC SURGEON FOR A PLANNED SURGERY. THIS TOOK PLACE 22SEP2020. THE FOLLOWING PROCEDURES WERE PERFORMED, POSTERIOR SPINAL FUSION OF L2,-L5, A WIDE DECOMPRESSIVE LAMINECTOMY, BILATERAL FACETECTOMY, L2-L3, L3-L4, L4-L5 WITH DECOMPRESSION OF THE L3-L5 NERVE ROOT. VERTEBROPLASTY L2-L5, LEFT ILIAC CREST BONE MARROW ASPIRATION AND APPLICATION OF 30ML OF BETA TRICALCIUM PHOSPHATE AND LOCAL AUTOLOGOUS BONE. SUBJECT 7 DAYS IN THE HOSPITAL POST OPERATIVELY. Subject also Had Covid testing prior to surgery tha was negative.' reason for change: Per Query Resolution Query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	12 Nov 2020 19:01:48
Query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	12 Nov 2020 12:25:06
Query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	12 Nov 2020 12:24:58

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.'	Jennifer Molstead (b) (4)	(b) (4) 12 Nov 2020 12:24:54
answered with 'updated' (Site from Safety). Query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 12 Nov 2020 12:24:42
DataPoint Un-verified.	Jennifer Molstead (b) (4)	(b) (4) 12 Nov 2020 12:20:39
User entered 'SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE.WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS GREATER THAN 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, Subject also had Chest x-ray which was negative, A MRI of Lumbar Spine that showed the worsening of Spinal Stenosis. Subject did have lab work, but results were unremarkable. Subject had consult with orthopedic surgeon for a planned Surgery. This took place 22Sep2020. The following procedures were performed, Posterior Spinal Fusion of L2,-L5, A Wide Decompressive Laminectomy, Bilateral Facetectomy, L2-L3, L3-L4, L4-L5 with decompression of the L3-L5 nerve root. Vertebroplasty L2-L5, Left Iliac Crest Bone Marrow aspiration and application of 30ML of beta tricalcium phosphate and local Autologous bone. Subject 7 days in the hospital post operatively.' reason for change: Per Query Resolution	Jennifer Molstead (b) (4)	(b) (4) 12 Nov 2020 12:20:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1863 of 2777



US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[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. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:35:02
User opened query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:34:53
User opened query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:34:44
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:34:35
User opened query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 17:34:17
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:10:52
User closed query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:10:47

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:10:44
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:10:43
User closed query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	04 Nov 2020 15:10:41
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available. ' answered with 'HAVE NOT RECEIVED RECORDS YET' (Site from Safety).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:36:54
Query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available. ' answered with 'HAVE NOT RECEIVED RECORDS YET' (Site from Safety).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:36:48
Query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available. ' answered with 'HAVE NOT RECEIVED RECORDS YET' (Site from Safety).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:36:43

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available. ' answered with 'HAVE NOT RECEIVED RECORDS YET' (Site from Safety).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:36:35
Query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available. ' answered with 'HAVE NOT RECEIVED RECORDS YET' (Site from Safety).	Traci Hull (b) (4) (b) (4)	03 Nov 2020 15:36:18
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:33:31
User opened query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:33:22
User opened query 'PV Query: Please report medically relevant physical exam findings. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:33:13
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:32:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range. Please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	03 Nov 2020 14:32:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:02:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:02:11
User closed query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:02:07
User closed query 'PV Query: Please report medically relevant physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:02:03
User closed query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable. ' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 19:01:56
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Still Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:08:21

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' answered with 'Still Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:08:19
Query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range.' answered with 'Still Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:08:16
Query 'PV Query: Please report medically relevant physical exam findings.' answered with 'Still Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:08:14
Query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable.' answered with 'Still Awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	29 Oct 2020 22:08:11
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 20:29:21
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications (including steroids) to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication).' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 15:16:08
User opened query 'PV Query: Please provide results of any relevant laboratory (CBC, chemistry) and diagnostic test results (X-ray, CT, MRI, etc). Please provide units and reference range.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 15:15:52
User opened query 'PV Query: Please report medically relevant physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 15:14:38

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify whether a ESR or CRP were performed and provide results, if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Sep 2020 15:14:03
User closed query 'PV Query: Please report medically relevant physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:30:49
User closed query 'PV Query: Please provide the pain scale used when the patient reported pain as 27 (i.e. 0 to 10, etc).' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:30:46
User closed query 'PV Query: Please confirm if lower back spasms was considered part of medical history (prior to onset of study) or an adverse event. If MH, please add to MH eCRF. If AE, please report in EDC.' (Site from Safety).	(b) (4), (b) (6)	14 Sep 2020 20:30:43
Query 'PV Query: Please report medically relevant physical exam findings.' answered with 'awaiting medical records' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:21:22
Query 'PV Query: Please provide the pain scale used when the patient reported pain as 27 (i.e. 0 to 10, etc).' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:21:10
Query 'PV Query: Please confirm if lower back spasms was considered part of medical history (prior to onset of study) or an adverse event. If MH, please add to MH eCRF. If AE, please report in EDC.' answered with 'updated' (Site from Safety).	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:20:59
User entered 'SUBJECT HAS A HISTORY OF BACK SPASMS. ON 23AUG2020 THE PAIN WAS SO BAD THAT THE PATIENT WENT TO THE URGENT CARE.WHEN ASKED WHAT HER PAIN LEVEL WAS SHE STATED IT WAS greater than 10. SHE WAS TRANSPORTED TO THE HOSPITAL WHERE SHE THEN SPENT 2 NIGHTS. SHE WAS GIVEN AN INTRAVENOUS INJECTION OF STEROIDS, OF WHICH SHE DID NOT KNOW THE NAME. AWAITING RECORDS.' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	(b) (4) 14 Sep 2020 01:19:55
Query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:42:49

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1869 of 2777

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:22:36

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Sep 2020 18:42:47
User opened query 'PV Query: Please report medically relevant physical exam findings.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:33:13
User opened query 'PV Query: Please provide the pain scale used when the patient reported pain as 27 (i.e. 0 to 10, etc).' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:33:06
User opened query 'PV Query: Please confirm if lower back spasms was considered part of medical history (prior to onset of study) or an adverse event. If MH, please add to MH eCRF. If AE, please report in EDC.' (Site from Safety).	(b) (4), (b) (6)	30 Aug 2020 17:32:14
User opened query 'Per ETRTR: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 17:18:29
User opened query 'Per ETRTR: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from CRA).	(b) (4), (b) (6)	27 Aug 2020 17:18:13
User entered 'Subject has a history of back spasms. On 23Aug2020 the pain was so bad that the patient went to the urgent care.when asked what her pain level was she stated it was a 27. She was transported to the hospital where she then spent 2 nights. She was given An intravenous injection of steroids, of which she did not know the name. Awaiting records.'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:48:55



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Aug 2020 19:48:55

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
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: Neuritis sciatic - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:34:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:34:41
Data point term sent to Coder	System	13 Apr 2021 15:30:42
User entered 'SIATIC NERVE PAIN'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '1 Apr 2021'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:22:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:29:52

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:22:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

US3402212

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:22:36

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	03 May 2021 22:58:17
User closed query 'Per CDM Review: Correct Action with IP is NA. ' (Site from DM).	(b) (4)	
Query 'Per CDM Review: Correct Action with IP is NA. ' answered with 'PER QUERY UPDATED ACTION TO NOT APPLICABLE' (Site from DM).	(b) (4), (b) (6)	01 May 2021 08:23:19
DataPoint Un-verified.	Tammy Kohn (b) (4)	30 Apr 2021 13:22:01
	(b) (4)	
Signature has been broken.	Tammy Kohn (b) (4)	30 Apr 2021 13:21:57
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	30 Apr 2021 13:21:57
User opened query 'Per CDM Review: Correct Action with IP is NA. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 23:10:32
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
	(b) (4)	
User entered 'None (NONE)'	Tammy Kohn (b) (4)	13 Apr 2021 15:29:52
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'I'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tammy Kohn (b) (4)	13 Apr 2021 15:29:52



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:29:52
	(b) (4)	

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Apr 2021 15:29:52

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54

US3402212

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:22:36

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as SOC: Renal and urinary disorders, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	13 Apr 2021 16:44:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:44:39
Data point term sent to Coder	System	13 Apr 2021 15:31:42
User entered 'KIDNEY STONES'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '13 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
User entered empty.	System	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '23 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
User entered empty.	System	13 Apr 2021 15:30:50



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Not Related (NOT RELATED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'None (NONE)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50



**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'l'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:48:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
User entered '0'	System	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54
User entered '0'	System	13 Apr 2021 15:30:50

**US3402212**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 12:56:54



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:22:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	06 Nov 2020 23:04:35
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 13:49:12

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: PRAMIPEXOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:55:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:55:25
Data point term sent to Coder	System	05 Aug 2020 13:50:54
User entered 'PRAMIPEXOLE'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'RESTLESS LEG SYNDROME'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'I'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:54
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 13:50:27
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 13:50:27
User entered 'UN UNK 2015' reason for change: Data Entry Error	Tarin Gordon (b) (4)	05 Aug 2020 13:50:27
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	05 Aug 2020 13:50:18
User entered 'UU UNK 2015' (non-conformant).	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:50:18
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:50:18

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:50:18

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 13:50:18

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, PRODUCT: CINNAMOMUM VERUM, PRODUCTSYNONYM: CINNAMON [CINNAMOMUM VERUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:27:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 23:27:03
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 13:51:57
User entered 'CINNAMON'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '1000'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:33
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 13:51:08
	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:51:08



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:51:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:51:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 13:51:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 18:38:48
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 18:38:48
	(b) (4)	
Data point term sent to Coder	System	03 Oct 2020 18:37:53
Coding entries removed.	Jennifer Molstead (b) (4)	03 Oct 2020 18:37:41
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ALENDRONATE SODIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:57:00
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 17:57:00
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 13:51:57
User entered 'ALENDRONATE SODIUM'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'OStEOPOROSIS' reason for change:	Jennifer Molstead (b) (4)	03 Oct 2020 18:37:41
New Information	(b) (4)	
User entered 'OSEOPOROSIS'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '35'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'every week (QS)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:40
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:43
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 13:51:55
	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:51:55

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:51:55

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:51:55

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	05 Aug 2020 13:51:55

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:11:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:11:11
Data point term sent to Coder	System	05 Aug 2020 14:10:13
User entered 'VITAMIN D3'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:09:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '2000'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'IU (IU)'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:46
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:37
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:09:17
	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:09:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:09:17



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:09:17

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:51:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 14:51:16
Data point term sent to Coder	System	05 Aug 2020 14:11:16
User entered 'LASIX'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:10:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'EDEMA BILATERAL FEET'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '20'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:52
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:25
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:10:30
	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:10:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:10:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:10:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTS YNonym: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:13:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:13:01
Data point term sent to Coder	System	05 Aug 2020 14:12:17
User entered 'MULTIVITAMIN'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:11:52

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'SUPPLEMENT'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'I'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'tablet (TABLET)'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:11:52

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:00:59
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:17
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:11:52
	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:11:52



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:11:52

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:11:52

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:11:52

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: SEMAGLUTIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:14:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 04:14:10
Data point term sent to Coder	System	05 Aug 2020 14:13:19
User entered 'SEMAGLUTIDE'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '.5'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'every week (QS)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Subcutaneous (SUBCUTANEOUS)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:04
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:10
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:12:40
	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:12:40

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:12:40

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:13:54
User coded data point as Term Coded data point by	(b) (4)	
User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:13:54
Data point term sent to Coder	System	05 Aug 2020 14:13:18
User entered 'SIMVASTATIN'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'HYPERLIPIDEMIA'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '40'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:10
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:20:04
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:13:16
	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:13:16

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:13:16

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:13:16

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:13:16

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:13:16



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:13:16

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:21:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	05 Aug 2020 14:21:58
Data point term sent to Coder	System	05 Aug 2020 14:20:30
Data point term sent to Coder	System	05 Aug 2020 14:14:19
User entered 'ASPIRIN'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'CARDIAC PROPHYLAXIS'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '81'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	05 Aug 2020 14:19:50
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	05 Aug 2020 14:14:04
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty; reason for change Data Entry Error	Tarin Gordon (b) (4)	05 Aug 2020 14:19:50
	(b) (4)	
User entered '81'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:18
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:19:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2010'	System	05 Aug 2020 14:14:04
	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:14:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:14:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:14:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:14:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
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)	03 Oct 2020 18:41:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 18:41:49
	(b) (4)	
Data point term sent to Coder	System	03 Oct 2020 18:40:54
Coding entries removed.	Jennifer Molstead (b) (4)	03 Oct 2020 18:40:03
	(b) (4)	
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)	10 Aug 2020 14:57:20
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 14:57:20
	(b) (4)	
Data point term sent to Coder	System	05 Aug 2020 14:15:23
User entered 'LOSARTAN'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Per MM, Please revise the indication or explain' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 14:59:55
Query 'Per MM, Please revise the indication or explain' answered with 'Updated' (Site from DM).	Jennifer Molstead (b) (4)	03 Oct 2020 18:40:11
User entered 'Hypertension' reason for change: Per Query Resolution	(b) (4)	
	Jennifer Molstead (b) (4)	03 Oct 2020 18:40:03
User opened query 'Per MM, Please revise the indication or explain' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	28 Sep 2020 12:29:05
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '100'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 06:22:47
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 18:16:58
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 18:16:51
User entered 'UN UNK 2015' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	18 Nov 2020 18:16:51
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 18:14:35
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:32
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:19:16
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:15:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:15:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:15:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
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)	05 Aug 2020 14:18:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Aug 2020 14:18:00
Data point term sent to Coder	System	05 Aug 2020 14:17:25
User entered 'GABAPENTIN'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
Query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY (e.g., Generalized, Spine, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:35:01
User opened query 'Per DM CLR: Please update the indication to reflect the location of DIABETIC NEUROPATHY (e.g., Generalized, Spine, Both Hips, Right Knee, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:04:16
User entered 'DIABETIC NEUROPATHY'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '300'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:18:49
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:16:59
	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:16:59

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:16:59

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:16:59

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:16:59

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:16:59



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 14:19:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 14:19:59
Data point term sent to Coder	System	05 Aug 2020 14:18:27
User entered 'MELOXICAM'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:17:32

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
Query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	30 Sep 2020 12:35:11
User opened query 'Per DM CLR: Please update the indication to reflect the location of OSTEOARTHRITIS (e.g., Generalized, Both Knees, Right Hip, etc). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 12:04:44
User entered 'OSTEOARTHRITIS'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:17:32

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '15'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:44
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:18:42
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:17:32
	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:17:32

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:17:32



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:17:32

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:17:32

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
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)	05 Aug 2020 14:19:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 14:19:59
Data point term sent to Coder	System	05 Aug 2020 14:18:26
User entered 'CARVEDILOL'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:18:25

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'HYPERTENSION'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '6.25'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:18:25

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'twice daily (BID)'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	14 Aug 2020 16:01:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ONGOING' (Site from System).	Tarin Gordon (b) (4)	05 Aug 2020 14:18:35
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
User entered 'UN UNK 2015'	System	05 Aug 2020 14:18:25
	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Aug 2020 14:18:25

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 14:18:25

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Aug 2020 14:18:25

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: ASCORBIC ACID (VITAMIN C), INCL. COMBINATIONS, ATC: ASCORBIC ACID (VITAMIN C), PLAIN, PRODUCT: ASCORBIC ACID, PRODUCTSYNONYM: VITAMIN C [ASCORBIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:42:45
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:42:45
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 11:41:59
User entered 'Vitamin C'	Jennifer Molstead (b) (4)	12 Nov 2020 11:41:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Dietary Supplement'	Jennifer Molstead (b) (4)	12 Nov 2020 11:41:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '500'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:41:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:41:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'UN UNK 2015'	Jennifer Molstead (b) (4)	12 Nov 2020 11:41:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:22:36**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:41:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 11:41:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 11:41:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 11:41:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: VITAMIN E NOS, PRODUCTSYNONYM: VITAMIN E [VITAMIN E NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:43:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:43:44
Data point term sent to Coder	System	12 Nov 2020 11:43:00
User entered 'Vitamin E'	Jennifer Molstead (b) (4)	12 Nov 2020 11:42:11
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:15:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 10:27:50
Query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 17:55:58
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 17:55:50
User entered 'Yes (Y)' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 17:55:50
User opened query 'Per DM CLR: Prophylaxis=NO. However, please note CM Indication is either a Supplement/Vitamin/Contraceptive/used for general health or prophylaxis. Please review if the Prophylaxis field is more appropriately ticked as Yes. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:19:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Dietary Supplement'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '100'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU (IU)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:42:11
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'UN UNK 2015'	Jennifer Molstead (b) (4)	12 Nov 2020 11:42:11
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:42:11

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 11:42:11

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 11:42:11

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	12 Nov 2020 11:42:11



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 09:45:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Jan 2021 09:45:16
Data point term sent to Coder	System	25 Jan 2021 20:22:03
Coding entries removed.	Tammy Kohn (b) (4)	25 Jan 2021 20:21:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Jan 2021 21:01:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Jan 2021 21:01:51
Data point term sent to Coder	System	22 Jan 2021 17:04:52
Coding entries removed.	Tammy Kohn (b) (4)	22 Jan 2021 17:04:43
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:53:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Nov 2020 11:53:44
Data point term sent to Coder	System	12 Nov 2020 11:53:01
User entered 'Oxycodone'	Jennifer Molstead (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:53:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per CDM re-query: Response noted; However per previous query, please update the term to reflect 'worsening' as there is a AE with "Worsening spinal stenosis". Please update else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 09:00:42
Query 'Per CDM re-query: Response noted; However per previous query, please update the term to reflect 'worsening' as there is a AE with "Worsening spinal stenosis". Please update else clarify. ' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 20:22:05
User entered 'PAIN ASSOCIATED WITH WORSENING SPINAL STENOSIS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	25 Jan 2021 20:21:55
User closed query 'Per DM CLR: Please update the indication to reflect the WORSENING SPINAL STENOSIS this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:32:40
User opened query 'Per CDM re-query: Response noted; However per previous query, please update the term to reflect 'worsening' as there is a AE with "Worsening spinal stenosis". Please update else clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 05:32:38
Query 'Per DM CLR: Please update the indication to reflect the WORSENING SPINAL STENOSIS this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'DATA UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:04:51
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:04:43
User entered 'PAIN ASSOCIATED WITH SPINAL STENOSIS' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	22 Jan 2021 17:04:43

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the WORSENING SPINAL STENOSIS this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	22 Jan 2021 06:53:27
	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 11:52:37
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '5'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'three times daily (TID)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:00:21
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:02:28
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4) Traci Hull (b) (4)	24 Nov 2020 16:02:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 20:55:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 20:55:54
Query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:02:36
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:02:28
User entered '25 Aug 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:02:28
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User opened query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:05:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User closed query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 12:26:28
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	12 Nov 2020 12:26:28
User entered 'No (N)' reason for change: Data Entry Error	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:26:28
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 11:52:37
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:52:37



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User entered '3'	System	12 Nov 2020 11:52:37

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User entered '1'	System	12 Nov 2020 11:52:37

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:06
User entered '804 (804)'	System	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:22:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 21:22:35
Data point term sent to Coder	System	12 Nov 2020 12:28:14
User entered 'Cyclobenzaprine'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:00:39
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:03:23
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 16:03:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:00:44
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:00:42
Query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:03:29
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:03:23
User entered '25 Aug 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:03:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User opened query 'Per source - Not ongoing, End date is 25 Aug 2020. Please verify and update.' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:05:59
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:27:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User entered '1'	System	12 Nov 2020 12:27:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User entered '1'	System	12 Nov 2020 12:27:30

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:15
User entered '804 (804)'	System	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:18:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:18:37
Data point term sent to Coder	System	12 Nov 2020 12:29:15
User entered 'Dexamethasone'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '4'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'three times daily (TID)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:29:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User entered '3'	System	12 Nov 2020 12:29:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User entered '1'	System	12 Nov 2020 12:29:04

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:20
User entered '804 (804)'	System	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTI-DEMENTIA DRUGS, ATC: ANTICHOLINESTERASES, PRODUCT: DONEPEZIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:41:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:41:38
Data point term sent to Coder	System	12 Nov 2020 12:31:16
User entered 'Donepezil'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 10:29:39
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'This is correct Donepezil can be used (offl abel) for spinal stenosis' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:48:02
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:19:57
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 12:30:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User entered '1'	System	12 Nov 2020 12:30:20

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User entered '1'	System	12 Nov 2020 12:30:20



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:27
User entered '804 (804)'	System	12 Nov 2020 12:30:20

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:33:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:33:42
Data point term sent to Coder	System	12 Nov 2020 13:20:37
User entered 'Heparin'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '5,000'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU (IU)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:20:26



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered '2'	System	12 Nov 2020 13:20:26

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered '1'	System	12 Nov 2020 13:20:26

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:37
User entered '804 (804)'	System	12 Nov 2020 13:20:26

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:01:59
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'CORRECT AS IS' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	Traci Hull (b) (4)	09 Apr 2021 18:38:54
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	02 Apr 2021 12:37:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4), (b) (6)	
Data point term sent to Coder	Coder Import (b) (4)	30 Dec 2020 19:07:20
Data point term sent to Coder	(b) (4)	
Coding entries removed.	System	30 Dec 2020 18:52:53
	System	30 Dec 2020 18:51:51
	Tammy Kohn (b) (4)	30 Dec 2020 18:50:57
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:13:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:13:39
Data point term sent to Coder	System	12 Nov 2020 13:22:39
User entered 'Insulin Aspart'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:54:19
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 18:25:06
User entered 'TYPE II DIABETES' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:51:57
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'data updated' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:51:07
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:50:57
User entered 'type 1 diabetes' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:50:57
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:20:23
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '100/4'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU/ML'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'four times daily (QID)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User entered '4'	System	12 Nov 2020 13:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User entered '1'	System	12 Nov 2020 13:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:50
User entered '804 (804)'	System	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:01:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:01:48
Data point term sent to Coder	System	12 Nov 2020 13:35:58
User entered 'Potassium Chloride'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 10:29:11
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'POTASSIUM CHLORIDE CAN BE USED AS AN OFF LABEL USE FOR SPINAL STENOSIS' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:57:28
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:20:41
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'meq'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:35:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User entered '1'	System	12 Nov 2020 13:35:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User entered '1'	System	12 Nov 2020 13:35:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:13:57
User entered '804 (804)'	System	12 Nov 2020 13:35:35



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
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: VALSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:56:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 04:56:48
Data point term sent to Coder	System	12 Nov 2020 13:40:02
User entered 'valsartan'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 10:31:20
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'VALSARTAN IS AN OFF LABEL USE FOR SPINAL STENOSIS' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 18:58:29
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:20:51
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '160'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:39:10

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User entered '1'	System	12 Nov 2020 13:39:10



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User entered '1'	System	12 Nov 2020 13:39:10

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:05
User entered '804 (804)'	System	12 Nov 2020 13:39:10

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:41:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 13:41:46
Data point term sent to Coder	System	12 Nov 2020 13:41:02
User entered 'Acetaminophen'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '650'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:40:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User entered empty.	System	12 Nov 2020 13:40:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User entered empty.	System	12 Nov 2020 13:40:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:09
User entered empty.	System	12 Nov 2020 13:40:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:19:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:19:36
Data point term sent to Coder	System	12 Nov 2020 13:43:03
User entered 'Dextrose'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25/50'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:01:13
User entered 'Other (OTHER)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:09:02
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:08:21
User entered 'mg (mg)' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:08:21
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per source dosing unit - G/mL. Please verify and update accordingly. ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 21:01:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:01:15
User entered 'G/ML' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:09:02
Query 'Per source dosing unit - G/mL. Please verify and update accordingly. ' answered with 'UPDATED' (Site from CRA).	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:08:33
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:08:21
DataPoint Un-verified.	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:07:42
User entered 'G/ML' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	24 Nov 2020 16:07:42
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User opened query 'Per source dosing unit - G/mL. Please verify and update accordingly. ' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 15:09:15
User entered 'G/MG'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 13:42:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User entered empty.	System	12 Nov 2020 13:42:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User entered empty.	System	12 Nov 2020 13:42:23

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:15
User entered empty.	System	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 07:03:10
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'CORRECT AS IS' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of WORSENING TYPE II DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	Traci Hull (b) (4)	09 Apr 2021 18:40:07
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	02 Apr 2021 12:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4), (b) (6)	
Data point term sent to Coder Coding entries removed.	Coder Import (b) (4)	30 Dec 2020 19:02:19
	(b) (4)	
DataPoint Verified.	Coder Import (b) (4)	30 Dec 2020 19:02:19
	(b) (4)	
	System	30 Dec 2020 19:01:55
	Tammy Kohn (b) (4)	30 Dec 2020 19:00:59
	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 15:12:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2398 of 2777

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:15:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:15:50
Data point term sent to Coder	System	12 Nov 2020 14:05:17
User entered 'glucagon'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:54:41
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 10:30:32
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'UPDATED' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 19:01:05
DataPoint Un-verified.	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 19:00:59
User entered 'TYPE II DIABETES' reason for change: Data Entry Error	Tammy Kohn (b) (4) (b) (4)	30 Dec 2020 19:00:59
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 05:21:11
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening of spinal stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '1/1'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:04:39

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User entered empty.	System	12 Nov 2020 14:04:39

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User entered empty.	System	12 Nov 2020 14:04:39



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:20
User entered empty.	System	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM HYDROXIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:11:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:11:38
Data point term sent to Coder	System	12 Nov 2020 14:26:41
User entered 'Magnesium Hydroxide'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '30'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mL (mL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:26:35



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User entered '1'	System	12 Nov 2020 14:26:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User entered '1'	System	12 Nov 2020 14:26:35

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:25
User entered '804 (804)'	System	12 Nov 2020 14:26:35

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:10:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:10:39
Data point term sent to Coder	System	12 Nov 2020 14:34:53
User entered 'Morphine'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '2/1'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:22:36**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:34:38

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User entered empty.	System	12 Nov 2020 14:34:38

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User entered empty.	System	12 Nov 2020 14:34:38

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:31
User entered empty.	System	12 Nov 2020 14:34:38

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:07:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 05:07:39
Data point term sent to Coder	System	12 Nov 2020 14:36:54
User entered 'Ondansetron'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening spinal stenosis'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '4/2'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'MG/ML'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Apr 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 14:36:05

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User entered empty.	System	12 Nov 2020 14:36:05

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User entered empty.	System	12 Nov 2020 14:36:05

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (29)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:35
User entered empty.	System	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:29
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
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 Jan 2021 08:13:01
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 Jan 2021 08:13:01
Data point term sent to Coder	System	19 Jan 2021 19:35:11
User entered 'OXYCODONE IR'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:33
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'WORSENING SPINAL STENOSIS'	Traci Hull (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '5'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:41
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:39
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'three times daily (TID)'	Traci Hull (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:43
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:47
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '23 Aug 2020'	Traci Hull (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:51
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:53
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '25 Aug 2020'	Traci Hull (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:58:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
User entered '3'	System	19 Jan 2021 19:34:24

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
User entered '1'	System	19 Jan 2021 19:34:24



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (30)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:39
User entered '804 (804)'	System	19 Jan 2021 19:34:24

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
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 HYPERTENSION; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 00:57:01
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 HYPERTENSION; update Con Med indication or provide clarification. ' answered with 'NO WORSENING OF HYPERTENSION INSURANCE NO LONGER COVERS THE OTHER MEDICATION.' (Site from DM).	Tammy Kohn (b) (4) (b) (4)	08 Mar 2021 13:21:16
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 HYPERTENSION; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 07:19:29
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, EXCL. THIAZIDES, ATC: SULFONAMIDES, PLAIN, PRODUCT: CHLORTALIDONE, PRODUCTSYNONYM: CHLORTHALIDONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Jan 2021 19:36:09
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 Jan 2021 19:36:09
Data point term sent to Coder	System	19 Jan 2021 19:35:11
User entered 'CHLORTHALIDONE'	Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:35:06
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:13
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'HYPERTENSION'	Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '25'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:35:06
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:53
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'once daily (QD)'	Traci Hull (b) (4)	19 Jan 2021 19:35:06



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:55
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:35:06
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:57
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Traci Hull (b) (4) (b) (4)	19 Jan 2021 19:35:06

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 13:59:59
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4)	
	Traci Hull (b) (4)	19 Jan 2021 19:35:06
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:26
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '07 Dec 2020'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:28
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:30
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Yes (Y)'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	Traci Hull (b) (4)	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:34
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Traci Hull (b) (4)	19 Jan 2021 19:35:06



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 19:35:06

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (31)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 19:35:06

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:46
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	07 Apr 2021 10:47:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:47:29
Data point term sent to Coder	System	01 Apr 2021 15:22:52
User entered 'DHLORTHALI'	Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:51
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'HYPERTENSION'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:05:53
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '12.5'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:13
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:15
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'once daily (QD)'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:17
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:28
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:22
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	01 Apr 2021 15:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:30
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:22:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:32
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '2 Mar 2021'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:34
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:39
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:22:08

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (32)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:47
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 06:52:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 06:52:42
Data point term sent to Coder	System	13 Apr 2021 15:32:43
User entered 'AMOXICILLIN'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'KIDNEY STONES'	Tammy Kohn (b) (4)	13 Apr 2021 15:32:17



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '875'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:55
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:06:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'twice daily (BID)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:01
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:03
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:05
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:07
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '16 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:09
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:12
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '26 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:32:17

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:40:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:32:22
User entered 'No (N)'	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:32:17
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
User entered '2'	System	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
User entered '1'	System	13 Apr 2021 15:32:17

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (33)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:55
User entered '804 (804)'	System	13 Apr 2021 15:32:17

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:22
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 08:43:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:43:46
Data point term sent to Coder	System	13 Apr 2021 15:40:54
User entered 'TIZANIDINE'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:24
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:25
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'KIDNEY STONES'	Tammy Kohn (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:27
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '2'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:29
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:33
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'three times daily (TID)'	Tammy Kohn (b) (4)	13 Apr 2021 15:40:50

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:35
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:37
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:43
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '16 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:44
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:46
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '26 Mar 2021'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:40:50

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:22:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:07:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
User entered '3'	System	13 Apr 2021 15:40:50

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
User entered '1'	System	13 Apr 2021 15:40:50



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (34)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:14:59
User entered '804 (804)'	System	13 Apr 2021 15:40:50

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:17
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: METHYLPREDNISOLONE, PRODUCTSYNONYM: MEDROL [METHYLPREDNISOLONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:51:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 12:51:48
User signature succeeded.	Frank Eder (b) (4) (b) (4)	15 Apr 2021 00:03:43
Data point term sent to Coder	System	13 Apr 2021 15:43:57
User entered 'MEDROL PREDNISONE'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:23
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:28
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'SCIATIC NERVE PAIN'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '4'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:08:34
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:46
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:48
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'once daily (QD)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:22:36

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:09:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:10:11
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '8 Apr 2021'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:10:14
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:10:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:12:01
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '12 Apr 2021'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:03
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:12:12
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	Tammy Kohn (b) (4)	13 Apr 2021 15:43:03



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 15:43:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 15:43:03

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (35)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 15:43:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:22:36

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:33
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 16:58:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 16:58:45
Data point term sent to Coder	System	13 Apr 2021 15:45:03
User entered 'TRAMADOL'	Tammy Kohn (b) (4) (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:39
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:41
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'SCIATIC NERVE PAIN'	Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:44
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '50'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:46
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58



US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:47
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:49
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'as needed (PRN)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:51
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:54
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:56
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:13:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '01 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:44:13
User entered '8 Apr 2021'	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:43:58
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:00
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:02
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:04
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '06 Apr 2021' reason for change: Data Entry Error	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:44:13
User entered '13 Apr 2021'	(b) (4)	
	Tammy Kohn (b) (4)	13 Apr 2021 15:43:58
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:06
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:43:58

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (36)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:43:58

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:22:36

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:28
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
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.	(b) (4) Coder Import (b) (4)	13 Apr 2021 17:01:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 17:01:09
Data point term sent to Coder	System	13 Apr 2021 15:46:05
User entered 'HYDROCODONE/ACETAMINOPHEN'	Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:29
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:31
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'SCIATIC NERVE PAIN'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:36
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '5/325'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:22:36

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:38
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'mg (mg)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:22:36

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:40
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:41
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'as needed (PRN)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:22:36

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:43
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:45
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Oral (ORAL)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:50
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:52
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '8 Apr 2021'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19



**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:55
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered '0'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:14:58
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'Yes (Y)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:15:00
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered empty.	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19
	(b) (4)	

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 14:15:02
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
User entered 'No (N)'	(b) (4) Tammy Kohn (b) (4)	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:45:19

**US3402212**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (37)**

**Generated On: 09 Jun 2021 17:22:36**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 15:45:19

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:22:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:32:42
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:22:27
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Molstead (b) (4)	12 Nov 2020 11:37:05
User entered 'No (N)'	Traci Hull (b) (4)	03 Sep 2020 20:51:22



US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	15 Apr 2021 00:03:43
	(b) (4)	
Signature has been broken.	Tammy Kohn (b) (4)	13 Apr 2021 15:41:43
	(b) (4)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 11:37:40
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'MRI Lumbar Spine'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:37:40

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:37:40

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 11:37:40
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:37
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered '23 Aug 2020'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:38:06

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:37
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Chest XRay'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:38:06

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:37
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:38:06

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:37
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered empty.	Jennifer Molstead (b) (4) (b) (4)	12 Nov 2020 11:38:06



US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '23 Aug 2020'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:40:54

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'LUMBAR SPINE XRAY'	(b) (4) Traci Hull (b) (4) (b) (4)	01 Dec 2020 20:40:54

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	(b) (4)	01 Dec 2020 20:42:37
Comment added 'CORRECT AS IS'.	System	01 Dec 2020 20:42:37
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	Traci Hull (b) (4)	01 Dec 2020 20:41:24
User entered 'Adverse Event (AE)'	(b) (4)	01 Dec 2020 20:40:54
	System	01 Dec 2020 20:40:54
	Traci Hull (b) (4)	01 Dec 2020 20:40:54
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:38
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty; reason for change Per Query Resolution	(b) (4)	
	Traci Hull (b) (4)	01 Dec 2020 20:42:37
User entered 'WORSENING OF SPINAL STENOSIS'	(b) (4)	
	Traci Hull (b) (4)	01 Dec 2020 20:40:54
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4) Jennifer Molstead (b) (4)	03 Dec 2020 13:19:04
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Posterior spinal fusion L2, L3, L4, L5,'	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:19:04
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:19:04

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:40
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:19:04
	(b) (4)	



**US3402212**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 09 Jun 2021 17:22:36**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4) Jennifer Molstead (b) (4)	03 Dec 2020 13:19:38
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Wide decompressive laminectomy, Bilateral Facetectomy L2-L5 with decompression of L 3, L4, L5 nerve root.'	(b) (4) Jennifer Molstead (b) (4)	03 Dec 2020 13:19:38

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:19:38

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:43
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:19:38
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:20:20
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Vertebroplasty L2, L3, L4. L5'	(b) (4) Jennifer Molstead (b) (4)	03 Dec 2020 13:20:20

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:20:20

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:46
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:20:20
	(b) (4)	



US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:22:18
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4) (b) (4)	08 Apr 2021 23:31:27
User entered 'left Iliac Crest Bone Marrow Aspiration and application of 30ml of beta tricalcium phosphate and local autologous bone'	Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:22:18

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:22:18

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:48
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:22:18
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:34:25
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Lumbar Spine XRay'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:34:25

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	03 Dec 2020 13:34:25

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:51
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	03 Dec 2020 13:34:25
	(b) (4)	



US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '25 Aug 2020'	(b) (4) Jennifer Molstead (b) (4)	22 Dec 2020 11:51:56
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Complete Blood COunt'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:51:56

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:51:56

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:54
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:51:56
	(b) (4)	

**US3402212**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (10)**

**Generated On: 09 Jun 2021 17:22:36**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	22 Dec 2020 11:52:56

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'complete metabolic profile'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:52:56

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:52:56

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:55
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:52:56
	(b) (4)	



**US3402212**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (11)**

**Generated On: 09 Jun 2021 17:22:36**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '22 Sep 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:54:42
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:54:42

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:54:42

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:28:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:54:42
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:00
DataPoint Verified.	(b) (4), (b) (6) Ndibe (2395 - 20 Apr 2021 16:11:25 uindibe1)	
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '23 Sep 2020'	(b) (4) Jennifer Molstead (b) (4)	22 Dec 2020 11:54:58
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:54:58

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:54:58

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (12)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:00
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:54:58
	(b) (4)	



**US3402212**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (13)**

**Generated On: 09 Jun 2021 17:22:36**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '24 Sep 2020'	(b) (4) Jennifer Molstead (b) (4)	22 Dec 2020 11:55:10

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:55:10

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:55:10

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (13)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:03
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:55:10
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:22:36

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered '25 Sep 2020'	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:55:24
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:22:36

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'complete blood count'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:55:24

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:22:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered 'Adverse Event (AE)'	(b) (4) Jennifer Molstead (b) (4) (b) (4)	22 Dec 2020 11:55:24

fb

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (14)

Generated On: 09 Jun 2021 17:22:36

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:29:11
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:11:25
User signature succeeded.	Frank Eder (b) (4)	08 Apr 2021 23:31:27
User entered empty.	(b) (4)	
	Jennifer Molstead (b) (4)	22 Dec 2020 11:55:24
	(b) (4)	



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:22:36**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:55
User entered '26/Aug/2020 10:04'	System	26 Aug 2020 14:04:47

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:22:36

**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.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'I'	(b) (4), (b) (6)	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:22:36**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:58:55
User entered '14/Sep/2020 15:43'	System	14 Sep 2020 19:43:32

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:22:36

**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.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
User entered 'I'	(b) (4), (b) (6)	14 Sep 2020 19:43:32

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:22:36**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Nov 2020 20:29:52
User entered '13/Nov/2020 13:44'	System	13 Nov 2020 13:44:11

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:22:36

**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.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:53
User entered 'I'	(b) (4), (b) (6)	13 Nov 2020 13:44:11

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:22:36**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 15:13:54
User entered '23/Nov/2020 20:13'	System	23 Nov 2020 20:13:21

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:22:36

**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.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:27:38
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:13:56
User entered 'I'	(b) (4), (b) (6)	23 Nov 2020 20:13:21



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered		
'USA-US059-2020-MRNA-1273-P301000001'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Yes (Y)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'No (N)'	System	26 Aug 2020 14:04:15



US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Frank'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Mary Jane Faith'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Eder'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Bagunas'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '1290 Upper Front Street'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '3636 Robin St. Anak Pawis,'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'Binghamton'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered 'Cainta'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered 'NY'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '40'	System	26 Aug 2020 14:04:15

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Un-reviewed for Safety.	System	14 Sep 2020 21:43:07
Amendment Manager: User entered '13901'	System	14 Sep 2020 21:43:07
Reviewed for Safety.	(b) (4), (b) (6)	26 Aug 2020 14:04:41
User entered '1900'	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:22:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:31:29
Comment added 'this is not something i can fix'.	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Un-reviewed for Safety.	(b) (4)	
	Jennifer Molstead (b) (4)	16 Sep 2020 17:47:57
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered 'US' (non-conformant).	System	26 Aug 2020 14:04:47

**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:22:36**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	22 Dec 2020 17:27:54
User entered '4'	System	23 Nov 2020 20:13:21
User entered '3'	System	13 Nov 2020 13:44:11
User entered '2'	System	14 Sep 2020 19:43:32
User entered '1'	System	26 Aug 2020 14:04:47



**US3402212**

**Folder: SAE USA-US059-2020-MRNA-1273-P301000001**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 17:22:36**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 13:49:41
User entered '22/Dec/2020 12:27'	System	22 Dec 2020 17:27:54

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:22:36

**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.	Frank Eder (b) (4)	26 Apr 2021 22:49:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 13:49:48
User entered 'I'	(b) (4), (b) (6)	22 Dec 2020 17:27:54