

US3402212 (Prod: Meridian Clinical Research, LLC)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:25:19

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US3402212

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:19

[Participant ID](#)

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

US3402212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

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 ☒
	Amendment 2 ☐
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:19

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:19

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

Condition	MODERATE OBESITY
Start date (dd MMM yyyy)	UN UNK 1953
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

Condition	OSTEOPOROSIS
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

Condition	DEGENERATIVE JOINT DISEASE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	_____

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

Condition	BILATERAL FOOT EDEMA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

Condition	DIABETIC NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

Condition	OSTEOARTHRITIS, SPINE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

Condition	RESTLESS LEG SYNDROME
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
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)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

Were vital signs assessed?	Yes ☒
	No ☐
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 ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	36.3 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	64 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

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.

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Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs) False

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	4 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Height	163.0 cm
Weight	98.6 kg

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

Height	163.0 cm
Weight	98.6 kg
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

Height	163.0 cm
Weight	98.6 kg
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
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 ☒ Axillary ☐ Other ☐
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

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	4 AUG 2020
Collection time (<i>00:00-23:59</i>)	09:27 (24 HR)
Collection date and time (derived)	4 AUG 2020 09:27

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:19

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

		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: 26 Nov 2020 09:25:19

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 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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 ☒

US3402212

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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)

Generated On: 26 Nov 2020 09:25:19

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	4 SEP 2020
Collection time (<i>00:00-23:59</i>)	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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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 ☒

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Yes ☐	
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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

Were vital signs assessed?	Yes ☒
	No ☐
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 ☒
	Axillary ☐
	Other ☐
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

Generated On: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:15 (24 HR)
Collection date and time (derived)	13 OCT 2020 09:15

US3402212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 103
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

12 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 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: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 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: 26 Nov 2020 09:25:19

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 166

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 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: 26 Nov 2020 09:25:19

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 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: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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 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: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 187

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

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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04 FEB 2021 00:01

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08 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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15 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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22 FEB 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2021 00:01

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01 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 215
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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08 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

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

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11 MAR 2021 00:01

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15 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

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12 APR 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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 contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the 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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 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: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 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: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 341

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

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

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

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

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

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

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

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13 SEP 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

27 JAN 2022 00:01

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31 JAN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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10 FEB 2022 00:01

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14 FEB 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

Date and time of submission

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17 FEB 2022 00:01

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21 FEB 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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24 FEB 2022 00:01

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28 FEB 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

Date and time of submission

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US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

Date and time of submission

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21 MAR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

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

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24 MAR 2022 00:01

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28 MAR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

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04 APR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

Date and time of submission

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07 APR 2022 00:01

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11 APR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Date and time of submission

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14 APR 2022 00:01

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18 APR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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21 APR 2022 00:01

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25 APR 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

12 MAY 2022 00:01

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16 MAY 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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19 MAY 2022 00:01

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23 MAY 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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26 MAY 2022 00:01

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30 MAY 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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02 JUN 2022 00:01

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06 JUN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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09 JUN 2022 00:01

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13 JUN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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16 JUN 2022 00:01

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20 JUN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

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27 JUN 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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04 JUL 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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11 JUL 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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18 JUL 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

Please contact your study clinic immediately. Click below to confirm that you have read this 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: 26 Nov 2020 09:25:19

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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: 26 Nov 2020 09:25:19

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3402212

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

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 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3402212

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:25:19

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

US3402212

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:25:19

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3402212

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:19

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)

Generated On: 26 Nov 2020 09:25:19

AEID	USA-US059-2020-MRNA-1273-P30 1000001
Adverse event	WORSENING SPINAL STENOSIS
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)	23 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
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 ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	23 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	25 AUG 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	341 of 2180

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☒ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ☒ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☒ Dose Delayed ☐ Investigational Product ☐ Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

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

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

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.

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:19

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)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:19

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 ☐
Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☒
	804	☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2010
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2015
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

Name of Medication	OXYCODONE
Prophylaxis	Yes ☐ No ☒
Indication	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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived)	3
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

Name of Medication	INSULIN ASPART
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING SPINAL STENOSIS
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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☐
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020
Was this medication taken for solicited event?	Yes ☐
	No ☒
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

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	
Route of administration	Q4H Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived) _____	
Interval Dosage Unit Number (derived) _____	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

Name of Medication	GLUCAGON
Prophylaxis	Yes ☐ No ☒
Indication	WORSENING OF SPINAL STENOSIS
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 ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

	Intramuscular	☒
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐	No ☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	803 ☐
	804 ☒	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

Respiratory (Inhalation)	☐
Intralesional	☐
Intraperitoneal	☐
Nasal	☐
Vaginal	☐
Rectal	☐
Intravenous	☒
Intravenous Bolus	☐
Intravenous Drip	☐
Other	☐
If route of administration is Other, specify _____	
Start date (dd MMM yyyy)	23 AUG 2020
Start date completely unknown	False
Ongoing?	Yes ☐ No ☒
If not Ongoing, End date (dd MMM yyyy) 25 AUG 2020	
Was this medication taken for solicited event?	Yes ☐ No ☒
Separate Dosage Number (derived) _____	
Interval Dosage Unit Number (derived) _____	
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

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 ☐ Intramuscular ☐

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☒
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	23 APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	25 AUG 2020	
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:19

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:25:19

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
23 AUG 2020	MRI LUMBAR SPINE	Adverse Event	
23 AUG 2020	CHEST XRAY	Adverse Event	

US3402212

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

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

Generated On: 26 Nov 2020 09:25:19

SAEID	USA-US059-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	4

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:25:19

SAEID	USA-US059-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	4
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)

Generated On: 26 Nov 2020 09:25:19

SAEID	USA-US059-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	4
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)

Generated On: 26 Nov 2020 09:25:19

SAEID	USA-US059-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	4
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)

Generated On: 26 Nov 2020 09:25:19

SAEID	USA-US059-2020-MRNA-1273-P301000001
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
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)	4
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

Audit

US3402212 (Prod: Meridian Clinical Research, LLC)

US3402212

Form: Participant Creation

Generated On: 26 Nov 2020 09:25:19

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3402212'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 13:19:27

US3402212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:22:17

US3402212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 13:19:27

US3402212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:22:17

US3402212

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	05 Aug 2020 13:22:17

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1941' reason for change: Data Entry Error	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: 26 Nov 2020 09:25:19

[Age](#)

Audit	User	Time (GMT)
User entered '79'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '79'	System	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Sex](#)

Audit	User	Time (GMT)
User entered 'Female (F)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

White

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

Unknown

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:25:19

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:13

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered '2020'	System	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 1 (1)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:28

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	04 Aug 2020 13:19:27

US3402212

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:25:19

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:25:19

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:34

US3402212

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:25:19

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:23:30

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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.	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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2010'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2010'	System	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2010'	System	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:24:13

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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.	Coder Import (b) (4) (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) (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) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1953'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 1953'	System	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '1953'	System	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:24:40

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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.	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 13:25:08
User entered 'OSTEOPOROSIS'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:01

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

Condition

Audit	User	Time (GMT)
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. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 15:00:36
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)	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)	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. ' answered with 'updated' (Site from DM).	Jennifer Molstead (b) (4)	03 Oct 2020 18:41:45
Coding entries removed.	Jennifer Molstead (b) (4)	03 Oct 2020 18:41:33
User entered 'DEGENERATIVE JOINT DISEASE' reason for change: Per Query Resolution	Jennifer Molstead (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. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 20:55:47
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)	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)	05 Aug 2020 23:00:05
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

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:22

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	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) (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) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:25:40

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:26:07

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:27:36

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis spinal - version MedDRA\\23.0.	Coder Import (b) (4) (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) (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) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:28:01

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	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)	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)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:28:19

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	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.	(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)	05 Aug 2020 13:30:04
	(b) (4)	

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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), (b) (6)	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. (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: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:30:04

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Condition](#)

Audit	User	Time (GMT)
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) (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) (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) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
User entered '2015'	System	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:25:19

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:30:35

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:02'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020 09:02'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '163.0' cm	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: 26 Nov 2020 09:25:19

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
User entered '98.6' kg	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: 26 Nov 2020 09:25:19

BMI (xxx.x)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[BMI units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '130'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:41:58

US3402212

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:21

US3402212

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(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).		04 Sep 2020 12:18:01
User entered '4 Aug 2020'	Tarin Gordon (b) (4)	05 Aug 2020 13:42:21
	(b) (4)	

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[If No, what is the reason?](#)

Audit	User	Time (GMT)
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'UN UNK 1980'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:25:19

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:42:54

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Warehouse shipping and fulfillment centers](#) and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
User entered '1'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:25:19

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:36

US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	05 Aug 2020 13:43:49

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

What was the date of randomization? (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '04 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 13:25:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

What was the participant's randomization number?

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	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) [REDACTED]	04 Aug 2020 13:25:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	04 Aug 2020 13:25:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:25:19

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:46:04

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Height

Audit	User	Time (GMT)
User entered '163.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Weight

Audit	User	Time (GMT)
User entered '98.6' kg	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Height

Audit	User	Time (GMT)
User entered '163.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Weight

Audit	User	Time (GMT)
User entered '98.6' kg	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: 26 Nov 2020 09:25:19

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	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: 26 Nov 2020 09:25:19

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:02'	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: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	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: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	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: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	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: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	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: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Height

Audit	User	Time (GMT)
User entered '163.0' cm	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:25:19

Weight

Audit	User	Time (GMT)
User entered '98.6' kg	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: 26 Nov 2020 09:25:19

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	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: 26 Nov 2020 09:25:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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) (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)	05 Aug 2020 13:48:02
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		05 Aug 2020 13:47:49
User entered '10:45'	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
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) (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)	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)	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)	17 Sep 2020 12:28:56
Amendment Manager: User opened 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).	System	16 Sep 2020 23:42:07
User entered '35.0' C	Tarin Gordon (b) (4)	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	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: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '16'	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: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '124'	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: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '68'	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: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Aug 2020 13:47:49

US3402212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 16:57:24
User entered 'Yes (Y)'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:12

US3402212

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Tammy Kohn (b) (4)	18 Sep 2020 16:57:24
User entered '4 Aug 2020'	Tarin Gordon (b) (4)	05 Aug 2020 13:48:12

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '10:05'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '4 Aug 2020 10:05'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Tarin Gordon (b) (4) (b) (4)	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 14:11:58

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:32

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:32

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:27'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:32

US3402212

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Aug 2020'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:30'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Aug 2020 13:48:52

US3402212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:48:57

US3402212

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Aug 2020 13:48:57

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	05 Aug 2020 00:23:02
User entered '98.4'	System	05 Aug 2020 00:23:02

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	06 Aug 2020 00:26:40
User entered '97.6'	System	06 Aug 2020 00:26:40

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Aug 2020 00:26:40
User entered '05 Aug 2020 20:26'	System	06 Aug 2020 00:26:40

US3402212

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:22:43

US3402212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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 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).	System	19 Aug 2020 12:23:15
User entered '11 Aug 2020' reason for change: Data Entry Error	Traci Hull (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)	19 Aug 2020 12:22:43

US3402212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:22:43

US3402212

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:22:43

US3402212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:24

US3402212

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 12:23:24

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:40

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:40

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:40

US3402212

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:40

US3402212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	19 Aug 2020 12:23:48

US3402212

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 12:23:48

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 20:31:25

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 20:31:25

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 20:31:25

US3402212

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	25 Aug 2020 20:31:25

US3402212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	25 Aug 2020 20:31:31

US3402212

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 20:31:31

US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4) (b) (4)	04 Sep 2020 12:18:01

US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:01
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:01
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	04 Sep 2020 12:18:01

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	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: 26 Nov 2020 09:25:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '07:27'	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: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.2' F	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: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	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: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '113'	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: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '64'	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: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Timepoint](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	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: 26 Nov 2020 09:25:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:37'	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: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	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: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	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: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '62'	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: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	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: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	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: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	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: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	04 Sep 2020 13:25:06

US3402212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:34

US3402212

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:34

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered empty.	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '08:04'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Which arm was used to give treatment?

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jennifer Molstead (b) (4)	04 Sep 2020 12:18:33
	(b) (4)	

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:25:19

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 12:18:33

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:55

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:55

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '07:45'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:25:55

US3402212

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '4 Sep 2020'	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: 26 Nov 2020 09:25:19

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User entered '07:42'	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: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Lab Test](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	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: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 13:26:12

US3402212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	04 Sep 2020 13:26:19

US3402212

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 13:26:19

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:13:10
User entered '98.2'	System	06 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:21
User entered '98.0'	System	06 Sep 2020 23:58:21

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:18
User entered 'Yes (Y)'	System	08 Sep 2020 00:12:18

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:18
User entered '98.7'	System	08 Sep 2020 00:12:18

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:18
User entered '07 Sep 2020 20:12'	System	08 Sep 2020 00:12:18

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:18:51
User entered 'Yes (Y)'	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:18:51
User entered '98.6'	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:18:51
User entered 'No (N)'	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:18:51
User entered '08 Sep 2020 20:18'	System	09 Sep 2020 00:18:51

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:20:17
User entered 'Yes (Y)'	System	10 Sep 2020 00:20:17

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:20:17
User entered '98.1'	System	10 Sep 2020 00:20:17

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:20:17
User entered '09 Sep 2020 20:20'	System	10 Sep 2020 00:20:17

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:04
User entered 'Yes (Y)'	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:19

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:04
User entered '98.6'	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:04
User entered '10 Sep 2020 20:21'	System	11 Sep 2020 00:22:04

US3402212

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:15:20
User entered 'No (N)'	System	05 Sep 2020 00:15:20

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:15:20
User entered 'No (N)'	System	05 Sep 2020 00:15:20

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:15:20
User entered '04 Sep 2020 20:15'	System	05 Sep 2020 00:15:20

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:13:37
User entered '05 Sep 2020 20:13'	System	06 Sep 2020 00:13:37

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:53
User entered 'None (1)'	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:53
User entered 'No (N)'	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:53
User entered 'No (N)'	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:53
User entered 'None (1)'	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:58:53
User entered '06 Sep 2020 19:58'	System	06 Sep 2020 23:58:53

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:40
User entered 'No (N)'	System	08 Sep 2020 00:12:40

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:40
User entered 'No (N)'	System	08 Sep 2020 00:12:40

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:12:40
User entered '07 Sep 2020 20:12'	System	08 Sep 2020 00:12:40

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:15
User entered 'None (1)'	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:15
User entered 'No (N)'	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:15
User entered 'No (N)'	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:15
User entered 'None (1)'	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:15
User entered '08 Sep 2020 20:19'	System	09 Sep 2020 00:19:15

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:20:41
User entered 'None (1)'	System	10 Sep 2020 00:20:41

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:23
User entered 'No (N)'	System	11 Sep 2020 00:22:23

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:23
User entered 'No (N)'	System	11 Sep 2020 00:22:23

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:19

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

Please select one response below

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time Stamp](#)

Audit	User	Time (GMT)
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'	System	11 Sep 2020 00:22:23
User entered '10 Sep 2020 20:22'	System	11 Sep 2020 00:22:23

US3402212

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'None (0)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	05 Sep 2020 00:16:13
User entered 'No (N)'	System	05 Sep 2020 00:16:13

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'None (0)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered 'No (N)'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 00:14:08
User entered '05 Sep 2020 20:14'	System	06 Sep 2020 00:14:08

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:59:30
User entered 'None (0)'	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:59:30
User entered 'None (0)'	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:59:30
User entered 'No (N)'	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	06 Sep 2020 23:59:30
User entered '06 Sep 2020 19:59'	System	06 Sep 2020 23:59:30

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'None (0)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered 'No (N)'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	08 Sep 2020 00:13:10
User entered '07 Sep 2020 20:13'	System	08 Sep 2020 00:13:10

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'None (0)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'None (0)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'None (0)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'None (0)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'None (0)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered 'No (N)'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	09 Sep 2020 00:19:46
User entered '08 Sep 2020 20:19'	System	09 Sep 2020 00:19:46

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'None (0)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered 'No (N)'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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'	System	10 Sep 2020 00:21:23
User entered '09 Sep 2020 20:21'	System	10 Sep 2020 00:21:23

US3402212

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

HEADACHE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

FATIGUE

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:25:19

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
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'	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: 26 Nov 2020 09:25:19

NAUSEA/VOMITING

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

CHILLS

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Time stamp](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[PC Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 11:32:56

US3402212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 11:32:56

US3402212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 11:32:56

US3402212

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	14 Sep 2020 11:32:56

US3402212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	14 Sep 2020 11:33:00

US3402212

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 11:33:00

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:57:50

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '18 Sep 2020'	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:57:50

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:57:50

US3402212

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:57:50

US3402212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Tammy Kohn (b) (4) (b) (4)	18 Sep 2020 16:57:54

US3402212

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:57:54

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
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).	System	13 Oct 2020 13:40:44
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 13:40:21
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:40:21

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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).	System	13 Oct 2020 13:41:11
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.' answered by data change (Site from System).	System	13 Oct 2020 13:41:11
User entered '25 Sep 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	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).	System	13 Oct 2020 13:40:44
User entered '29 Sep 2020' reason for change: Per Query Resolution	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:40:44
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:40:21

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Not Made (CONTACT NOT MADE)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:40:21

US3402212

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:25:19

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered 'LEFT 3 VOICE MAIL MESSAGES WITH NO CALL BACK'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:40:21

US3402212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:41:15

US3402212

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 13:41:15

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:41:29

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
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) (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 COMEIN ON TIME' (Site from DM).	Tammy Kohn (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)	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)	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)	13 Oct 2020 13:41:29

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:41:29

US3402212

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:25:19

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 13:41:29

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:12'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.5' F	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User entered '14'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '123'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '64'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:25:19

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 13:44:44

US3402212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3402212

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:25:19

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:44:52

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:45:04

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:45:04

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '09:15'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:45:04

US3402212

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:25:19

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Traci Hull (b) (4) (b) (4)	13 Oct 2020 13:45:09

US3402212

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:25:19

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 13:45:09

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[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: '2020-10-12T16:46:22', User OID: 'PatientReportedOutcome (US3402212)', ODM File OID: 'a2174240-edd3-43db-9578-06695e9a66cd' User entered 'No (N)'	System	12 Oct 2020 20:46:46

US3402212

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

Have you been exposed to someone with 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: '2020-10-12T16:46:29', 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: 26 Nov 2020 09:25:19

[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: '2020-10-12T16:46:42', 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: 26 Nov 2020 09:25:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[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: '2020-11-09T21:29:26', 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: 26 Nov 2020 09:25:19

Have you been exposed to someone with 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: '2020-11-09T21:29:31', 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: 26 Nov 2020 09:25:19

[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: '2020-11-09T21:29:41', 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: 26 Nov 2020 09:25:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[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: '2020-11-15T08:29:48', 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: 26 Nov 2020 09:25:19

Have you been exposed to someone with 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: '2020-11-15T08:29:56', 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: 26 Nov 2020 09:25:19

[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: '2020-11-15T08:30:08', 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: 26 Nov 2020 09:25:19

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 Oct 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: 26 Nov 2020 09:25:19

[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 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 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: 26 Nov 2020 09:25:19

[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 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: 26 Nov 2020 09:25:19

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:19:28
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 12:19:28

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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 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: 26 Nov 2020 09:25:19

[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 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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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'	System	22 Nov 2020 14:40:30
User entered 'No (N)'	System	22 Nov 2020 14:40:30

US3402212

Folder: New Safety Follow Up Diary (1)

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Generated On: 26 Nov 2020 09:25:19

Have you been exposed to someone with 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'	System	22 Nov 2020 14:40:30
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: 26 Nov 2020 09:25:19

[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'	System	22 Nov 2020 14:40:30
User entered '22 Nov 2020 09:40:28'	System	22 Nov 2020 14:40:30

US3402212

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:25:19

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:23:13
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:42:49
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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 'USA-US059-2020-mRNA-1273-P301000001'	System	26 Aug 2020 14:04:15
User entered 'New'	(b) (4), (b) (6)	26 Aug 2020 14:04:15

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Adverse event](#)

Audit	User	Time (GMT)
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)	12 Nov 2020 13:19:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 13:19:46
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 12:21:13
DataPoint Un-verified.	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
	(b) (4)	
Coding entries removed.	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
	(b) (4)	
User entered 'WORSENING Spinal Stenosis' 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 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.	(b) (4), (b) (6)	07 Oct 2020 14:59:36
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).		

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Adverse event](#)

Audit	User	Time (GMT)
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." ' answered with 'Still waiting on medical records. Term correct as is' (Site from DM).	Jennifer Molstead (b) (4)	03 Oct 2020 18:45:04
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.	(b) (4), (b) (6)	23 Sep 2020 07:02:53
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).		
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) (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) (b) (4)	14 Sep 2020 16:27:51
Data point term sent to Coder	System	14 Sep 2020 01:20:26

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please consider updating event term to worsening of lower back spasms.' answered with 'updated' (Site from Safety). Coding entries removed.	Jennifer Molstead (b) (4)	14 Sep 2020 01:20:09
	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: 26 Nov 2020 09:25:19

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Severity](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Yes (Y)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered '1'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
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: 26 Nov 2020 09:25:19

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'No (N)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Not Related (NOT RELATED)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'None (NONE)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:17:01
DataPoint Un-verified.	Jennifer Molstead (b) (4)	12 Nov 2020 12:20:39
	(b) (4)	
User entered '1' 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 '0'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:56:26
User entered empty.	Jennifer Molstead (b) (4)	25 Aug 2020 19:48:55
	(b) (4)	

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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)	23 Nov 2020 20:40:37

US3402212

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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), (b) (6)	20 Nov 2020 18:06:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[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

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Folder: Adverse Events

Form: Adverse Events (1)

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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

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Folder: Adverse Events

Form: Adverse Events (1)

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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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

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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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

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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

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Folder: Adverse Events

Form: Adverse Events (1)

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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)	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)	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)	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)	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

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (1)

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[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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 19:48:55

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:25:19

[Medically Attended AE 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: 26 Nov 2020 09:25:19

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	25 Aug 2020 19:48:55

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:25:19

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:04:35
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:49:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (b) (4)	14 Aug 2020 04:55:25
Data point term sent to Coder	System	05 Aug 2020 13:50:54
User entered 'PRAMIPREXOLE'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'RESTLESS LEG SYNDROME'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '1'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:50:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:26
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).	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
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

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	05 Aug 2020 23:27:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 23:27:03
Data point term sent to Coder	System	05 Aug 2020 13:51:57
User entered 'CINNAMON'	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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'TYPE II DIABETES'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '1000'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:33
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).	System	05 Aug 2020 13:51:08
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	03 Oct 2020 18:38:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:38:48
Data point term sent to Coder Coding entries removed.	System Jennifer Molstead (b) (4)	03 Oct 2020 18:37:53 03 Oct 2020 18:37:41
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.	(b) (4) Coder Import (b) (4) (b) (4)	05 Aug 2020 17:57:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Aug 2020 17:57:00
Data point term sent to Coder User entered 'ALENDRONATE SODIUM'	System Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 13:51:57 05 Aug 2020 13:51:55

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'OStEOPOROSIS' reason for change: New Information	Jennifer Molstead (b) (4) (b) (4)	03 Oct 2020 18:37:41
User entered 'OSEOPOROSIS'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '35'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'every week (QS)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:40
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).	System	05 Aug 2020 13:51:55
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 13:51:55

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (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) (b) (4)	05 Aug 2020 14:09:17

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'SUPPLEMENT'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '2000'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'IU (IU)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:46
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).	System	05 Aug 2020 14:09:17
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:09:17

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'EDEMA BILATERAL FEET'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '20'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:52
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).	System	05 Aug 2020 14:10:30
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:10:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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, PRODUCTSYNONYM: 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

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'SUPPLEMENT'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '1'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'tablet (TABLET)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:00:59
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).	System	05 Aug 2020 14:11:52
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:11:52

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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) (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) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '.5'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Subcutaneous (SUBCUTANEOUS)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:04
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).	System	05 Aug 2020 14:12:40
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:12:40

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	05 Aug 2020 14:13:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	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) (b) (4)	05 Aug 2020 14:13:16

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'HYPERLIPIDEMIA'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '40'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:10
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).	System	05 Aug 2020 14:13:16
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:13:16

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (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.	Coder Import (b) (4) (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) (b) (4)	05 Aug 2020 14:14:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'CARDIAC PROPHYLAXIS'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '81'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	05 Aug 2020 14:14:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(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
User entered '81'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:18
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).	System	05 Aug 2020 14:14:04
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	05 Aug 2020 14:14:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	03 Oct 2020 18:41:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Oct 2020 18:41:49
Data point term sent to Coder Coding entries removed.	System Jennifer Molstead (b) (4)	03 Oct 2020 18:40:54 03 Oct 2020 18:40:03
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.	(b) (4) Coder Import (b) (4) (b) (4)	10 Aug 2020 14:57:20
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 14:57:20
Data point term sent to Coder User entered 'LOSARTAN'	System Tarin Gordon (b) (4) (b) (4)	05 Aug 2020 14:15:23 05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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	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)	28 Sep 2020 12:29:05
User entered 'TYPE II DIABETES'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '100'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	18 Nov 2020 18:16:58
DataPoint Un-verified.	(b) (4)	18 Nov 2020 18:16:51
User entered 'UN UNK 2015' reason for change:	Tammy Kohn (b) (4)	18 Nov 2020 18:16:51
Data Entry Error	(b) (4)	18 Nov 2020 18:14:35
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)	06 Nov 2020 23:09:29
DataPoint Verified.	(b) (4), (b) (6)	14 Aug 2020 16:01:32
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)	05 Aug 2020 14:19:16
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 14:15:03
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
User entered 'UN UNK 2010'	Tarin Gordon (b) (4)	05 Aug 2020 14:15:03

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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) (b) (4)	05 Aug 2020 14:16:59

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '300'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:38
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).	System	05 Aug 2020 14:16:59
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:16:59

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '15'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:44
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).	System	05 Aug 2020 14:17:32
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:17:32

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '6.25'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
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 16:01:50
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).	System	05 Aug 2020 14:18:25
User entered 'UN UNK 2015'	Tarin Gordon (b) (4)	05 Aug 2020 14:18:25

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 23:09:29
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
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
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

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '500'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Dietary Supplement'	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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '100'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU (IU)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Yes (Y)'	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: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
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
	(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 11:53:44
	(b) (4)	
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
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	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: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '5'	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: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	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: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'three times daily (TID)'	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: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	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: 26 Nov 2020 09:25:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	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: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	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: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	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: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:00:21
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:02:28
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 16:02:28
	(b) (4)	
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
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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 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)	24 Nov 2020 16:02:36
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:02:28
User entered '25 Aug 2020' reason for change: Per Query Resolution	Traci Hull (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)	12 Nov 2020 11:52:37

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	12 Nov 2020 12:26:28
	(b) (4)	
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)	12 Nov 2020 11:52:37
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:00:39
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:03:23
	(b) (4)	
User entered 'No (N)' reason for change: Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 16:03:23
	(b) (4)	
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
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed 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 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)	24 Nov 2020 16:03:29
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:03:23
User entered '25 Aug 2020' 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 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)	12 Nov 2020 12:27:30

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:27:30
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	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)	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)	12 Nov 2020 12:29:04

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '4'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'three times daily (TID)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:29:04
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 12:30:20
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 00:33:42
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:33:42
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 13:20:37
User entered 'Heparin'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '5,000'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU (IU)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'twice daily (BID)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:20:26
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
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) (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) (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) (b) (4)	12 Nov 2020 13:22:08

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '100/4'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'IU/ML'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'four times daily (QID)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:22:08
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 05:01:48
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:01:48
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 13:35:58
User entered 'Potassium Chloride'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '10'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'meq'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:35:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '160'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:39:10
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	12 Nov 2020 13:41:46
	(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 13:41:46
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 13:41:02
User entered 'Acetaminophen'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '650'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg (mg)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:40:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 00:19:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 00:19:36
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 13:43:03
User entered 'Dextrose'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25/50'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 21:01:13
User entered 'Other (OTHER)' reason for change:	Traci Hull (b) (4)	24 Nov 2020 16:09:02
Per Query Resolution	(b) (4)	
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:08:21
	(b) (4)	
User entered 'mg (mg)' reason for change: Per	Traci Hull (b) (4)	24 Nov 2020 16:08:21
Query Resolution	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

If dose unit is Other, specify

Audit	User	Time (GMT)
User closed query 'Per source dosing unit - G/mL. Please verify and update accordingly. ' (Site from CRA).	(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)	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)	24 Nov 2020 16:08:33
User entered empty; reason for change Per Query Resolution	Traci Hull (b) (4)	24 Nov 2020 16:08:21
DataPoint Un-verified.	Traci Hull (b) (4)	24 Nov 2020 16:07:42
User entered 'G/ML' reason for change: Per Query Resolution	Traci Hull (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)	12 Nov 2020 13:42:23

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 13:42:23
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	Coder Import (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)	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)	12 Nov 2020 14:04:39

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening of spinal stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '1/1'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'as needed (PRN)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intramuscular (INTRAMUSCULAR)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:04:39
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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)	13 Nov 2020 05:11:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:11:38
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 14:26:41
User entered 'Magnesium Hydroxide'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '30'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mL (mL)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'once daily (QD)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Oral (ORAL)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:26:35
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
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: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:10:39
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 05:10:39
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 14:34:53
User entered 'Morphine'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening Spinal Stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '2/1'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'mg/ml'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:34:38
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Worsening spinal stenosis'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '4/2'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'MG/ML'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'other (OTHER)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'q4h'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'Intravenous (INTRAVENOUS)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '23 Apr 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '0'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered '25 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:12:15
User entered 'No (N)'	Jennifer Molstead (b) (4)	12 Nov 2020 14:36:05
	(b) (4)	

US3402212

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 26 Nov 2020 09:25:19

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	12 Nov 2020 14:36:05

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:25:19

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'MRI Lumbar Spine'	Jennifer Molstead (b) (4)	12 Nov 2020 11:37:40
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:37:40
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:25:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered '23 Aug 2020'	Jennifer Molstead (b) (4)	12 Nov 2020 11:38:06
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:19

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Chest XRay'	Jennifer Molstead (b) (4)	12 Nov 2020 11:38:06
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:19

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered 'Adverse Event (AE)'	Jennifer Molstead (b) (4)	12 Nov 2020 11:38:06
	(b) (4)	

US3402212

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:25:19

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 17:07:57
User entered empty.	Jennifer Molstead (b) (4)	12 Nov 2020 11:38:06
	(b) (4)	

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: State

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
Reviewed for Safety.	(b) (4), (b) (6)	14 Sep 2020 19:43:13
User entered '1'	(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: 26 Nov 2020 09:25:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Nov 2020 13:43:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:58:55
User entered '1'	(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: 26 Nov 2020 09:25:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:13:09
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 20:29:53
User entered '1'	(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: 26 Nov 2020 09:25:19

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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 (b) (6)	System	26 Aug 2020 14:04:15

US3402212

Folder: SAE USA-US059-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 26 Nov 2020 09:25:19

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(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: 26 Nov 2020 09:25:19

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
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: 26 Nov 2020 09:25:19

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(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: 26 Nov 2020 09:25:19

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 15:13:56
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 20:13:21